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REAL TIME PHYSIOLOGICAL STATUS MONITORING (RT-PSM): ACCOMPLISHMENTS, REQUIREMENTS, AND RESEARCH ROADMAP

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REAL TIME PHYSIOLOGICAL STATUS MONITORING (RT-PSM): ACCOMPLISHMENTS, REQUIREMENTS, AND RESEARCH ROADMAP

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14. ABSTRACT
Real-time physiological status monitors (RT-PSM) are an important new category of military wearables in the individual Soldier's technological ecosystem. RT-PSM addresses a gap by providing individual Soldiers and small unit leaders with actionable information needed to ensure individual and squad performance readiness. This summary of accomplishments, requirements and research road-maps identifies what RT-PSM is and is not, how current capabilities can be used in current programs of record, and where future research should focus. Notable accomplishments include the development of a commercial criterion, FDA-certified wearable research tool, useful in acquiring data from Soldiers and Marines in training and operational environments performing their normal activities under stressful conditions. This has advanced development of algorithms and concepts of operation for various applications. Current implementation of RT-PSM for thermal-work strain monitoring includes technology transitions through the National Guard Bureau and the Program Executive Office Soldier Integrated Soldier Sensor System program.

15. SUBJECT TERMS
physiological monitoring; readiness index; Soldier/Marine status dashboard; technological ecosystem of the Soldier/Marine; thermal work strain index; alertness monitoring; biomechanical stress/fatigue monitoring; mood and cognition status monitoring; metabolism and energy expenditure monitoring; physiological limits; personal area network; squad area network

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GLOSSARY AND ABBREVIATIONS

PSM, RT-PSM, WPSM

The terms for Soldier wearable monitoring systems are used interchangeably in this report: Physiological Status Monitor (PSM), Warfighter Physiological Status Monitor (WPSM), and Real Time Physiological Status Monitor (RT-PSM).

"Warfighter" was added to the original PSM label in 1995 in order to distinguish the USAMRMC research effort from a plethora of commercial offerings. Many studies have been conducted with wearable systems that collected and stored data for later analyses; as systems have begun to transition to actual time measurements of soldier status monitoring, "real time" has been added (RT-PSM) to emphasize this capability.

Soldier, Marine

Research described in this report has involved Soldiers and Marines and the generic use of the term "Soldier" is used to represent both Soldiers and Marines, with all due respect to our Marine Corps friends.

Abbreviation	Definition
AFRL	Air Force Research Laboratory
AMEDD C&S	Army Medical Department Center and School
ANAM	Automated Neuropsychological Assessment Metric
ARL	Army Research Laboratory
ASD SO/LIC	Assistant Secretary of Defense Special Operations/ Low Intensity Conflict
ATEC	Army Test and Evaluation Center
ATO	Army Technology Objective
BAN	Body Area Networks
BAPL	Body Armor Protection Level
BBMD	Biophysics and Biomedical Modeling Division
BESS	Biomechanical Exoskeleton Simulator System
BIDs	Ballistic Impact Detector
BMIST-T	Biomedical Information System–Tactical
CBRNE	Chemical, Biological, Radiological, Nuclear and Explosive
CDD	Capability Development Document
CEP	Concept Experimentation Program
CEPF	Concept Exploration Program Funding
Commo	Communications
COTS	Commercial Off the Shelf
CPD	Capabilities Production Document
CPU	Central Processing Unit

Abbreviation	Definition
CRI	Compensatory Reserve Index
CST-WMD	Civil Service Team- Weapons of Mass Destruction
CTTSO	Combating Terrorism Technical Support Office
CWA	Chemical Warfare Agents
DARPA	Defense Advanced Research Projects Agency
DBBL	Dismounted Battlespace Battle Lab
DCAPS	Detection & Computational Analysis of Psychological Signals
DLW	Doubly Labeled Water
DOM	Drink-O-Meter
DST Group	Defence Science and Technology Group (Australia)
ECG	Electrocardiogram
EEG	Electroencephalogram
ESQ	Environmental Symptoms Questionnaire
FFI	Forsvarets forsknings institutt (Norwegian Defense Research Establishment)
FFRDC	Federally Funded Research and Development Center
FFW	Future Force Warrior
FTX	Field Exercise
GAO	Government Accountability Office (USA)
GFE	Government Furnished Equipment
GPS	Global Positioning System
GTRI	Georgia Tech Research Institute
HIPPA	Health Insurance Portability and Accountability Act (1996)
HSDA	Heat Strain Decision Aid
ICD	Initial Capabilities Document
IED	Improvised Explosive Device
ILIR	In-House Laboratory Independent Research
IMETS	Integrated Meteorological System
IPT	Integrated Research Team
IRBA	Institut de Recherche Biomédicale des Armées (Armed Forces Biomedical Research Institute) (France)
ISSS	Integrated Soldier Sensor System
LSDS	Life Sign Decision Support
LSDS	Life Sign Detection System
MCoE	Maneuver Center of Excellence (US Army - Ft. Benning)
MINIMEN	Minimalist Wearable Mesh Network
M_{loco}	Metabolic Costs of Locomotion
MOUT	Military Operations in Urban Terrain
NBC	Nuclear, Biological and Chemical
NGB	National Guard Bureau
NHANES	National Health and Nutrition Examination Survey)

Abbreviation	Definition
NHRC	Naval Health Research Center
NSF	National Science Foundation
NVG	Night Vision Goggles
OBAN	Open Body Area Network
OMPAT	Office of Military Performance Assessment Testing
ONR	Office of Naval Research (US)
OSD	Office of the Secretary of Defense
P^2NBC^2	Physiological and Psychological Effects of the NBC Environment and Sustained Operations on Systems in Combat
PAN	Personal Area Network
PEO	Program Executive Office
PII	Personally Identifiable Information
PM SPIE	Program Manager Soldier Protection & Individual Equipment
PMO MSS	Program Management Office Medical Support Systems
POTFF	Preservation of the Force and Families
PPG	Photoplethysmogram
PSI	Physiological Strain Index
PVT	Psychomotor Vigilance Test
RAD	Research Area Director
REM	Rapid Eye Movement
RER	Respiratory Exchange Ratio
ROPSM	Ranger Overwatch Physiological Status Monitor
RQ	Respiratory Quotient
SAN	Squad Area Network Communications
SBIR	Small Business Innovative Research Program
SECARMY	Secretary of the Army (US)
SFDF-LOE	Squad: Foundation of the Decisive Force - Limited Objective Experiment
SME	Subject Matter Expert
SoC	System on a Chip

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EXECUTIVE SUMMARY

Dismounted, foot-mobile Soldiers currently use a wide variety of wearable technologies, e.g., GPS (global positioning system) /PNT (position, timing, navigation), night vision goggles (NVGs), rangefinders, radios, other Nett Warrior items, etc. These wearable technologies, i.e., electronic systems carried and used by Soldiers, Sailors, Airmen and Marines, constitute the individual Soldier's technological ecosystem.

Real-time physiological status monitors (RT-PSM) are an important new category of modern military wearable technologies. RT-PSM wearables fill a gap by providing individual Soldiers and their immediate leadership with actionable physiological status information needed to ensure individual and squad health and performance/readiness. This survey of accomplishments, requirements and research road-maps identifies what RT-PSM is and is not, how current capabilities can be used in current programs of record, and where future research should focus.

The primary Soldier platform (i.e., Nett Warrior system) is complimented by several wearable applications. RT-PSM is one such application, and it provides readiness status information to small unit leaders. This information, as well as decision assist tools to the individual Soldier and small unit leader, represent "exobrain capabilities," i.e., knowledge gained from wearables or the web that enhance but do not replace good leader training and intuition.

The Army has a long history of research and development on wearable physiological monitoring systems. Notable accomplishments include the development of a commercial criterion, FDA-certified wearable research tool (Equivital, EQ-02; http://www.equivital.co.uk/). This system has been used extensively for field data acquisitions and refinement of algorithms and concepts of operation in various applications, beginning with thermal-work strain monitoring as the first component of a small unit leader readiness status indicator.

To date, the greatest payoff resulting from the development of this PSM system has been the ability to obtain physiological data on Soldiers and Marines in training and operational environments performing their normal functions under stressful conditions not easily reproducible in the laboratory. These datasets have helped guide changes in USMC work/rest doctrine, e.g., USMC rest procedures where half the squad opens up armor to accelerate cooling while other half guards, then trades, USMC reduction in soft armor to facilitate cooling], development of the body armor protection level (BAPL) concept and the development of concepts of operations (CONOPS) for the use of real time physiological readiness information of value to the Soldier and small unit leaders. Several implementations of the RT-PSM based on thermal-work strain monitoring are underway, including technology transitions through the National Guard Bureau (NGB) and the Program Executive Office (PEO) Soldier Integrated Soldier Sensor System (ISSS) program.

Capabilities to monitor readiness status of friendly forces, especially for a small unit leader, can expand rapidly once a DoD-centric open-architected PSM platform is in place for Soldiers in operational environments. Near-term targets include alertness/fitness for duty and musculoskeletal status (fatigue and impending musculoskeletal injury). Mid-term targets include neurocognitive status (mood and cognitive states) and in the longer-term, host defense responses (anticipation of impending illness). Existing technologies (i.e., sensors, predictive algorithms) make these readiness indicators feasible, but a concerted R&D program is required, which includes a commitment to the development and implementation of a common wireless PSM infrastructure. Beyond detection and status monitoring, RT-PSM has multiple applications, notably a decision support tool that would provide near- and long-term courses of action tailored to the individual.

While the focus of this report is on near-term applications that serve leaders and Soldiers, long-term applications and objectives include: casualty monitoring capabilities for the medic, health behavior self-monitoring tools for the Soldier, and environmental exposure documentation for force health protection.

INTRODUCTION

PURPOSE OF THIS REVIEW

This review is focused on wearable physiological sensors, the algorithms, models and user interfaces that extract and present actionable information for Soldiers and Marines. It summarizes more than two decades of research and technology efforts in this area at the U.S. Army Research Institute of Environmental Medicine (USARIEM) and through other closely related efforts. This review will emphasize: (1) knowledge that resulted from this research investment and the transition of products traceable to these efforts, (2) current requirements and research efforts and (3) an outline of plans to expand the development of RT-PSM capabilities for Soldiers and Marines.

The broad purpose of wearable monitoring is to acquire and interpret physiological data, thereby creating actionable information that protects and sustains military performance. In contrast, medical triage and tactical casualty care decision support systems are applied to casualties after a casualty event and are not used to optimize Soldier safety/ performance. Although the broad vision is that physiological monitoring will ultimately be extended to support far-forward casualty management (**Figure 1**), the first goal of wearable monitoring is to provide operational support to individuals and their leaders.

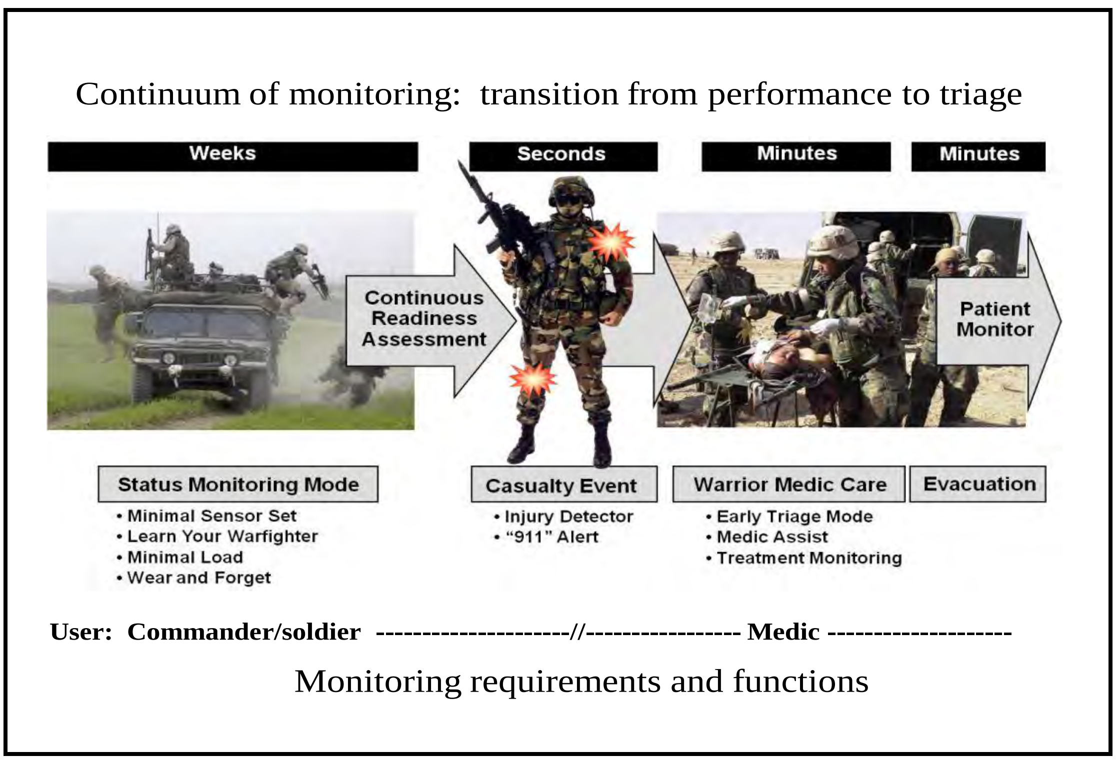

Figure 1. Concept for Soldier physiological monitoring systems (source: Friedl, 2008). This is based on the original PSM concept developed between Dr. Fred Hegge, (Director, Army Operational Medicine research program) and Dr. Reed Hoyt (USARIEM).

WHAT SOLDIER PHYSIOLOGICAL MONITORING (RT-PSM) DOES

RT-PSM is intended to provide actionable information concerning Soldier safety and performance for small unit leaders. Examples of the useful applications of RT-PSM are:

- Thermal strain and workload management
- Alertness and neurocognitive status assessments
- Physical fatigue management and avoidance, and early detection and pre-clinical mitigation of musculoskeletal injury
- Hydration and metabolic fuel management

These four Soldier performance parameters are inextricably interrelated; continued research is leading to deeper insights into more complex physiological relationships that also directly affect Soldier optimization (**Figure 2**). For example, information from work rate, thermal strain and workload management can also be used to modify dietary intake and manage body fuel stores, fitness and hydration to further optimize performance.

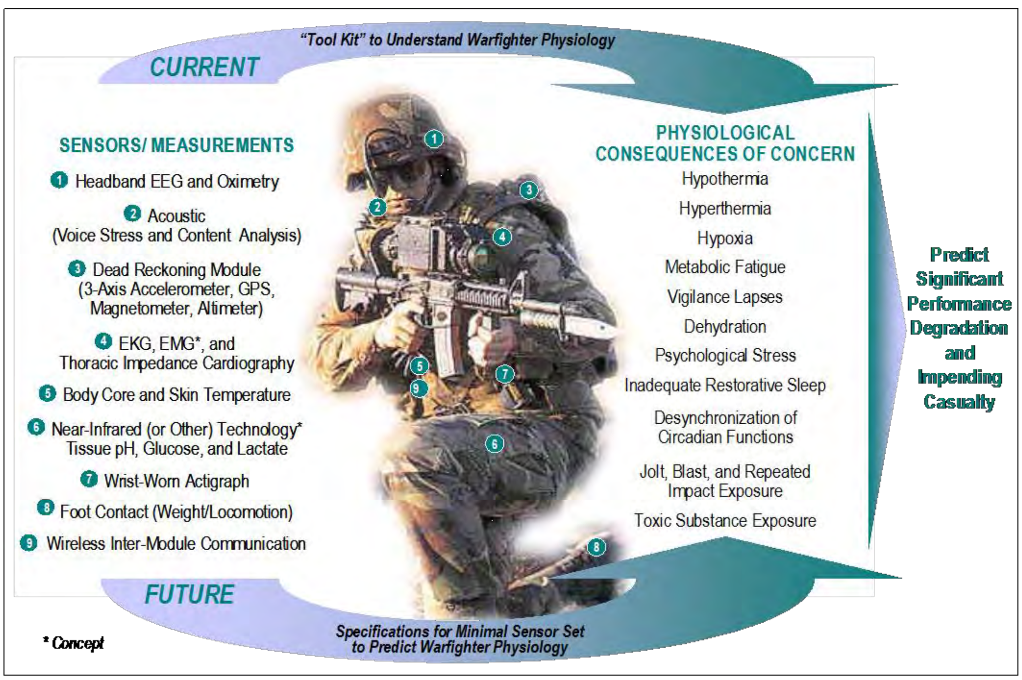

Figure 2. An early concept of wearable sensor data fusion to predict physiological outcomes of relevance to military training and operational environments (Figure source: Karl Friedl & Janet Reece, 1999).

WHAT SOLDIER PHYSIOLOGICAL MONITORING CURRENTLY DOES NOT DO

Warrior Medic Casualty Detection, Triage and Medical Management

Biomedical monitoring for performance and for casualty care are often confused and erroneously intertwined. These developmental efforts have highly distinct research objectives and regulatory requirements (**Table 1**). The information products serve different customers (small unit leaders versus medical providers). Nevertheless, Military Operational Medicine (MOM) and Tactical Combat Casualty Care (TCCC) applications share interests in certain sensor types: (e.g., oximetry/PPG) short range wireless communications, open-architecture standards and low-power encryption. The long-term concept is to provide a common wearable sensor system that extends from training and operational performance monitoring to tactical casualty alerts, triage and medical management capabilities (**Figure 1**).

Current TCCC research efforts including intramural programs at the U.S. Army Institute of Surgical Research, the Army Small Business Innovative Research (SBIR) programs (e.g., A16-052, Secure Wireless Disposable Pulse Oximeter Patch that Generates a PPG Waveform) and an Army Science and Technology Objective (STO) (STO R.MED.2016.20, “Tailored, Individualized Health and Performance Monitoring”), which intends to develop a method to detect and monitor hemorrhage through the use of PPG waveform to generate the compensatory reserve index (CRI). This hemorrhage detection capability is a component of Warrior Medic (Moulton et al. 2013). In addition, the En-Route Care PM has other hemorrhage management algorithm development efforts.

Force Health Protection Environmental Exposures Monitoring and Documentation

On-body environmental sensor systems provide information that, when integrated with RT-PSM data analyses, can provide additional insights and capabilities when operating in hazardous CBRNE environments. It will also serve a force health protection function involving acquisition and documentation of potentially harmful environmental exposures. These applications are currently viewed as post-product improvements of the PSM system platform because the current wearable TIC/TIM/Agent sensing capabilities are at low technology readiness levels and because the force health protection information must link to medical records, posing several HIPPA and PII regulatory challenges not yet addressed.

Table 1. Comparison of WPSM/PSM and Warrior Medic concepts

	WPSM/PSM concepts	Warrior Medic concepts
Objectives	Optimize performance and reduce non-battle injury risk	Detect, triage and medically manage casualties
First application(s)	Thermal-work strain feedback for work/rest cycles	Point of injury hemorrhage management
CONOPS	Mission-specific algorithms and plug-and-play sensor sets	Defined clinical protocols across levels of care
Primary research setting	Field training and operational environments (USARIEM)	Clinical laboratory (USAISR)
HARDWARE/SYSTEM		
Characteristic technology/sensor set	Minimal sensor set needed to provide actionable Soldier performance information	Medical standard of care devices used to guide medical treatment
Key sensor measurements	Heart rate, Tcore, activity, body position, Tskin, gait biomechanics	ECG, blood pressure, oxygen saturation, respiration, intracerebral pressure
Primary system integration lab	MIT Lincoln Laboratory & USARIEM	Commercial organizations
SOFTWARE/ALGORITHMS		
Signal processing	Mitigates motion artifacts from physical activity	Mitigates motion artifacts during patient transport
Data management requirements	Limited collection of individual health and performance status information to provide mission actionable information	Comprehensive collection of valid, clinically-relevant medical data for patient care and health record storage
Data quality requirements	Good enough to make accurate predictions	Must meet FDA standards
Key algorithms	Core temperature estimation from time series heart rate; thermal-work strain index	Hemorrhage detection and management algorithms (e.g., compensatory reserve index)
Primary research lab	USARIEM	USAISR
COMMUNICATIONS		
Who receives the information?	Soldier, small unit leader	Medic, medical care provider
Communications network	Intra-Soldier Wireless open body area network (OBAN)	Nearest Battalion Aid Station; write to individual medical record via TMDS
Data security	Tactically secure	Medical information protection regulated by HIPAA
Data encryption	Requires low power encryption	Existing encryption is likely adequate
Primary research lab	MIT Lincoln Laboratory	TATRC
OTHER CONSIDERATIONS		
Regulatory requirements	DoD VV&A	FDA approval
Basis of issue	Every Soldier	Every medic
Cost per system	Low	Moderate/High

An augmented physiological warning capability for RT-PSM, i.e., a system providing both physiological status and early warning of possible adverse exposure to potentially-harmful environments may develop more rapidly. This approach has similarities to the NSF ASSIST Center (https://assist.ncsu.edu) approach of monitoring the physiological effects of environmental exposures. The OSD (SO/LIC) Combating Terrorism Technical Support Office (CTTSO) and DTRA coordination of wearable environmental sensor development programs is likely to produce near-term outward-looking sensing technologies that, combined with RT-PSM, will provide important warnings and immediate status information in hazardous chemical and biological environments. This capability could be integrated through the technology platform already in development for thermal-work strain monitoring in Army National Guard Weapons of Mass Destruction Civil Support Teams (WMD-CSTs), and should leverage open-architected, ultra-low power System on Chip efforts currently underway (e.g., SBIRs for Ultra Low-Power System on a Chip (SoC) for Physiological Status Monitoring (PSM)).

Health Behaviors and Fitness Monitoring

The Army Medical Department Performance Triad (P3) initiative intended to improve Soldier exercise, sleep, and nutrition habits incorporates commercial off-the-shelf wearable technologies to help monitor physical activity and to motivate and reinforce health behaviors. The Special Operations Command (SOCOM) Preservation of the Force and Families (POTFF) initiative has developed their own wrist-worn monitoring system for similar purposes and the Office of Naval Research (ONR) has developed a new sleep-activity watch for shipboard health habits monitoring that accommodates normal movements of a ship. Physical fitness monitoring is not a primary objective of RT-PSM, and no Army RDT&E funding has been made available to support research in this area. Army research on energy expenditure needed for RT-PSM contributes to health and fitness monitoring concepts. For example, previous efforts led to development of the foot contact monitor prediction of energy expenditure associated with locomotion (Hoyt, Knapik, Lanza et al. 1994; Hoyt, Buller, Santee et al. 2004), and a fitness index from heart rate and foot contact time data has been described and validated (Weyand et al. 2001). Sleep monitoring developed by the Army is also foundational element of overall fitness monitoring (Redmond & Hegge, 1985).

VALUE OF THIS RESEARCH TO THE ARMY

Initial inspection of commercially available physiological monitoring systems could suggest the Army adopt and field one of these COTS solutions. Unfortunately, it is difficult to confirm performance of these COTS solutions as they may not provide scientifically valid data and are almost entirely “black box” proprietary systems and algorithms. Objective testing and evaluation of these commercial products by Army and DoD-affiliated organizations has demonstrated that precision and accuracy of commercial systems can vary widely, and the applications and outputs generally do not satisfy Army or USMC needs. Technology development is advancing so rapidly that studies can be quickly overtaken by better devices with new capabilities. For all of

these reasons, it is critical for the Army to develop its own PSM technological ecosystem, and have SMEs that are continuously identifying, evaluating and leveraging any valuable new extramural developments into the Solider-centric technological ecosystem. The DoD SMEs maintain close contact with the operational community, understand current and emerging military needs for RT-PSM and continuously work to shape emerging technologies to fulfill Army and USMC requirements. Furthermore, because the Army and Marine performance requirement for RT-PSM lies somewhere between the performance of commercial fitness systems and the performance of FDA-certified clinical monitoring systems, it is critical that RT-PSM development efforts strike the right balance of acceptability, precision, accuracy, scalability, size, weight, power and cost, while avoiding duplication and re-invention.

SECTION 1. ARMY RESEARCH ACCOMPLISHMENTS

Section 1 contents:

- Evolution of Army Wearables
- Research Drivers and Key Accomplishments
  - Response to Ranger Hypothermia Deaths in Training (Feb. 15, 1995)
  - Energy Metabolism and Work Effort Estimations
  - Remote Assessment of Sleep and Neurocognitive Status
  - Medical Casualty Detection Systems
  - Integrated WPSM-Initial Capability
  - Making Data Useful with Thermal Monitoring Algorithms

EVOLUTION OF ARMY WEARABLE SYSTEMS

In his 1959 novel, *Starship Troopers*, Heinlein provided a visionary concept of wearable monitoring where a small unit leader checks his squad's health status and identifies and withdraws a squad member with a fever (**Figure 3**). This served as an early "mark on the wall" for the development of a wearable Soldier monitoring system. The Army funded a development effort at Purdue University to actually create such a device, resulting in a heavy, wrist-mounted heart rate and activity monitor with a second box on the arm for telemetry (Tacker, 1989). Heinlein's science fiction concept of continuous heart rate and actigraphy measurements from a wearable wrist system has been realized and overtaken by currently available commercial systems (e.g., Apple Watch, BASIS, Mio etc.). While heart rate and activity monitoring represent interesting measurements, without interpretation the data are not particularly useful to a field commander.

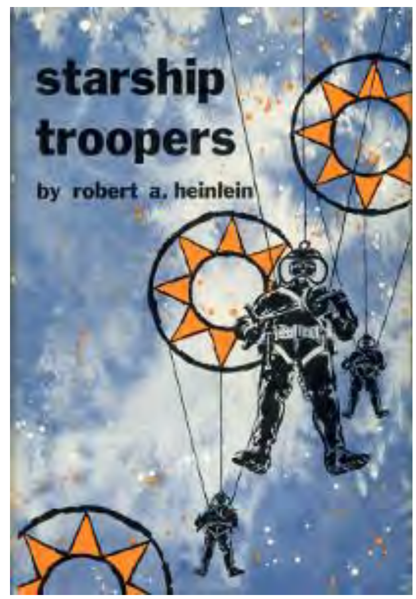

Figure 3. Robert Heinlein's 1959 book "Starship Troopers" provided a scientific concept of wearable physiological monitoring that inspired earlier Army research First Edition cover]

The Army has been a leader in physiological status monitoring research with more than two decades of field research by USARIEM. The Army research program resulted in development and validation of sensors and devices that acquire specific physiological data, notably the core temperature pill, which permits continuous measurements outside of the laboratory, and foot strike monitors, which use foot-ground contact time to accurately estimate the energy expenditure associated with locomotion. After development and testing of at least five major wearable sensor systems, these Army efforts directly resulted in specifications for a chest-worn system, the Equivital system (Hidalgo, Ltd, Cambridge, UK) that is currently the gold standard for untethered physiological monitoring. This wearable sensor technology has been used to collect unique and useful physiological data on Soldiers and Marines in training and operational settings outside of the artificial confines of a laboratory (**Figure 2**). In addition, these

efforts have led to the development of wearable systems, including sensors, signal processing algorithms, streaming data management methods, data transmission strategies and algorithms to convert data into actionable information addressing practical Army needs (**Figure 4**).

This body of field research was variously supported by In-house Laboratory Independent Research (ILIR) funding, Concept Exploration Program (CEP) funding and specific program initiatives, including Army Science and Technology efforts (STO IV.ME.1997.01 “Warfighter Physiological Status Monitoring” and the related, STO, “Warrior Medic Computer-Aided Diagnosis and Treatment”), Defense Technology Objectives (MD09J00ANE, “Advanced Medical Technology – Field Medical Support”) and Army Technology Objectives (“Warfighter Physiological Status Monitor – Initial Capability”). Other related efforts were made possible through targeted topics in the SBIR and STTR programs at Army and DoD and through several special multi-year program initiatives, including the Military Operational Medicine research program, Congressionally directed efforts in “Metabolic Monitoring Technologies” (minimally invasive metabolic markers) and “oculometric assessment of readiness” involving PMI Inc., Rockville, MD, and Eye-Com, Reno, NV) (**Table 2**).

The specific objectives of Army physiological monitoring efforts have frequently shifted in reaction to specific urgent needs (e.g., Ranger hypothermia deaths), specific leader interests (e.g., live-dead detection and ballistic impact detection) and novel research opportunities (e.g., ILIR and CEP funding). Transitioning PSM-related S&T products has been challenging due to continuously changing Soldier Modernization Program initiatives. For example, in 2004, the “Life Sign Detection System” development was coordinated with the Objective Force Warrior (OFW) program. In 2005, this became part of the system of systems for the Future Force Warrior (FFW). By 2008, the new target was the restarted Land Warrior (LW). Current transition efforts are linked by technology transition agreements (TTAs) to PM SPE ISSS, as part of Nett Warrior. Several cycles of leadership interest in physiological monitoring have occurred in the past 20 years, notably telemetry of vital signs, such as heart rate and body temperature; medic remote triage capabilities and automatic “911” alert capability; live-dead determination and ballistic impact detection and brain blast injury assessment from helmet sensors.

Advanced development for each of these capabilities has proven to be premature relative to the technology readiness and/or the acceptability of the technology to Soldiers,including squad and Soldier interest in keeping health and performance information squad-centric and ephemeral, i.e., leaving nothing left to tarnish the image of Soldiers in the event of something adverse. Generally, the concepts have been ahead of the research and engineering needed to enable PSM systems that are reliable, easy to use and provide valid and actionable information. With many lessons learned, the first implementation of real time physiological monitoring (RT-PSM) uses thermal-work strain monitoring to provide health and safety performance status during operation in hot environments.

Figure 4. Then and Now - physiological monitoring outside of the laboratory “in the wild”. In 1954, scientists at the Quartermaster Environmental Protection Research developed a telemetry system to monitor the physiological responses, including skin temperature, of volunteers in field tests of new uniforms and individual equipment (upper panel). In 2013, Mark Richter, Marine Expeditionary Rifle Squad, used the wearable Equivital EQ-02 system (Hidalgo Ltd) to document physiological responses to training in hot/wet tropical conditions. He is shown here using a handheld infrared moisture monitor to document uniform water content in Marines wearing new tropical uniforms during training at Camp Gonsalves, Okinawa (lower panel).

Table 2. PSM-Related Funded Programs

System	Intended functions	Company/Agency	Funding program/Year
Soldier Field Activity Monitoring System	Develop a practical wrist worn actigraph based on a novel cantilevered beam motion sensor	Precision Control Design, Inc.	USAMRDC grant 1983
Ranger Overwatch PSM (ROPSM)	Develop a PSM system with fuzzy logic analysis to detect hypothermia in Ranger course	SARCOS Corporation	DARPA 1995
Reduced Ship's Crew by Virtual Presence (RSVP)	Shipboard wireless sensor PSM tracking of sailors in SMART ship damage control	Draper labs, ARL, and multiple performers	NSWCCD 1996
Energy Requirements and Activity Patterns of Men and Women	Develop measurement techniques and characterize energy and activity in the field	Pennington Biomedical Research Lab	Army DWHRP grant 1995+
Biomedical Field Monitoring System	Develop Biostat system with sensor and data management functions used at Dugway PG	SAIC & Precision Control Design, Inc.	Army contract funding 1995+
Medic Warrior	Incorporate Medic Warrior into Land Warrior configuration, with "911" locator messaging	Raytheon Systems Co.	Land Warrior Program 1998
Crew Management Device	Develop "Military Sleep Watch 2000" based on wrist-worn actigraphy	Precision Control Design, Inc.	Army A97-118 SBIR 1997
Position Sensitive Physiologic Monitor	Modify dead reckoning module (DRM) for physiologic/motion data and locomotory energy costs	Point Research Corp./Honeywell	Army A98-102 SBIR 1998
Miniature Thermometer for Remote Monitoring	Increase data transmission reliability of multiplexed thermometer pill and skin patches	Minimitter Corp.	Army A00-064 SBIR 2000
Lifeguard	Develop prototype remote wearable vital signs monitor for astronauts, first responders	Stanford University	NASA-Ames ~2001
Technologies for Metabolic Monitoring research program	Develop minimally invasive sensor technologies for continuous analyte monitoring	Multiple performers	RAD3 program 2001-2006
Computational Microsystems for Biomedical sensors	Develop digital signal processing wrist actigraph with ballistic cardiogram	Precision Control Design, Inc.	Army A01-186 SBIR (Phase 1 only) 2001
Footstep Detection Sensor Type and Placement	Develop method to acoustically measure distance traversed from footsteps and distance between boots	Odic Incorporated	Army contract funding, 2001

System	Intended functions	Company/Agency	Funding program/Year
Wear-and-Forget ECG and Respiratory Monitor	Develop wearable system for cardiorespiratory monitoring outside of clinical settings	Minimitter Corp.	Army A02-180 SBIR 2002
Life Sign Decision Support (LSDS) Algorithms for WPSM	Develop fuzzy logic sensor data classification of states: “live,” “dead,” and “unknown”	GCAS, Inc.	DoD OSD02-DH01 SBIR 2002
Personal Area Network for WPSM	Develop prototype PSM for use in field data collection	Aware Inc.	Army A03-159 SBIR 2003
Programmable Wrist-Worn Environmental Stress Monitor	Develop wearable integrated sensors system to predict stress and performance	Precision Control Design, Inc.	Army A03-169 SBIR 2003
Body Worn “Band Aid” Monitor	Prototype miniaturized body-worn vital signs sensing for remote medical triage	CIMIT	Army/TATRC Congressional program 2003+
Warfighter PSM System Development	Develop integrated WPSM in coordination with U.S. Army	Hidalgo Ltd.	USAMRMC funding 2004-09
Wearable, Low Power Ballistic Impact Detection System	Develop low power wearable system to detect blast and ballistic wounding events	Quantum Applied Science & Research, Inc.	Army A05-163 SBIR 2005
Minimalist Short-Range Wearable for Soldier Training	Develop short range wireless network strategy and PSM systems dashboard display	Aware Inc & MIT Media Laboratory	Army A05-T028 STTR 2005 (Phase 1) 2005
Minimalist Wearable Mesh Network (MINIMEN) System	Develop PSM system linking wearable sensors, mesh networking and RF comms	Elintrix and Ohio State University	Army A05-T028 STTR 2005
Minimalist Short-Range Wearable Network for Training	Develop system that jointly considers issues of low power, low cost and wireless commo	Elintrix and San Diego State University	Army A05-T028 STTR 2005
Bidirectional Inductive On-Body Network (BIONET) for WPSM	Develop sensor links and processing nodes on-Soldier and non-RF links off-Soldier	Elintrix	DoD OSD06-H02 SBIR 2006 Phase 1 & 2
Volume-Sensing Personal Hydration System	Develop solid state noninvasive volume sensing for collapsible bladder canteen	Infoscitex Corp.	DoD OSD06-H02 SBIR 2006
Multi-Analyte Wearable Chemical Nanosensors for WPSM	Develop low power photonic-based sensor to differentiate/estimate VOC concentration	Elintrix and University of California, San Diego	Army A07-T035 STTR 2007 Phase 1 & 2
Develop More Next Generation of Equivital EQ-01/-02 Device	Reduce device surface area 25%; SEM thickness <9 mm; maintain EQ-01 capabilities; improve comfort under armor	Hidalgo Ltd.	Army contract 2009
Wearable Fiber Optic-Enabled Chemical Nanosensor Array	Develop metal-oxide sensors and electronic nose-based detection of TICs	Elintrix	Army A09-153 SBIR 2009 Phase 1 & 2

System	Intended functions	Company/Agency	Funding program/Year
Integrated Short Range Low Bandwidth Wearable Networking	Advance SPARNET to TRL6 with prototype network system in relevant environment	Elintrix and Innovative Wireless Technologies	Army contract 2011
Squad Area Network Communications (SAN)	Demonstrate SAN radio network and repeater node, sending physiological data	Innovative Wireless Technologies	Army contract 2011
Tool for Design and Evaluation of Body Wearable Devices	Quantify effect of assistive devices on agility, energy costs, and load carriage	CFD Research Corp.	Army A13-083 SBIR 2013
Biomechanical Exoskeleton Simulator System (BESS)	Model human-system interaction for prototyping of load carriage systems	RE2, Inc.	Army A13-083 SBIR 2013
Ultra Low-Power System on a Chip (SoC) for PSM	Develop ultralow power PSM SoC that senses, processes and communicates information	PsiKick	Army A14-052 SBIR 2014

RESEARCH DRIVERS AND KEY ACCOMPLISHMENTS

<u>Response to Ranger Hypothermia Deaths in Training (Feb 15, 1995)</u>

Four students died of hypothermia during the swamp phase of the Ranger course in 1977. When four more Ranger students died in the same training in 1995, physiological monitoring and GPS tracking of individuals became an urgent research priority. A GAO report on high risk training listed PSM as a corrective action in Ranger training (GAO NSAID-97-29, Jun 1997): *Recommendation #14. Develop personnel status monitoring system technology for possible use in Florida. Results: Completed. Experimental monitors tested in June 1996, but no procurement made.* The GAO report referred to an unpublished 5-day device test of the Ranger Overwatch PSM system.

1. Ranger Overwatch PSM (ROPSM)

A wearable monitoring solution was proposed by DARPA. There was an assumption that monitoring the physiological state of Ranger students in the field could be readily solved with existing technology and knowledge and that this industry demonstration would lead to a more comprehensive PSM system for the Army. DARPA (Program Manager, Don Jenkins) funded the Sarcos Corporation (www.sarcos.com) to develop a wearable vital signs system for casualty care monitoring and decision support, following Soldiers from injury through levels of care. The proprietary system was also intended to locate and identify friendly forces. USAMRMC co-funded the initial work, with projected deployment of 250 systems to Camp Rudder. With little return on investment, this represents a lost opportunity.

The technical approach for ROPSM relied on fuzzy logic analysis of skin temperature, tremor (tuned to shivering frequencies), heart rate, motor activity and environmental temperature to categorize individual risk of hypo- and hyperthermia and warn Ranger Instructors and medics. A test with anesthetized surgical patients compared skin and auditory canal temperature measurements and concluded that these sites accurately reflected esophageal temperature. PSM units with COTS spread spectrum radios worn by Ranger students were to be used to identify individuals, provide geolocation, determine physiological state, provide medical alerts, and connect to medical records. Signals would be transmitted through a series of radio towers to be established throughout the training areas (PSM Coordination Working Group, Oct 23, 1995).

Published scientific literature did not support the use of the chosen sensors, and the proposed fuzzy logic algorithm was not validated or verified for use in the field. The ROPSM system was included in field research protocols, but delivery dates for the equipment could not be established. The test protocol was eventually suspended (Memo from USARIEM to USAIC DBBL, Jan 30, 1997). An expert review panel concluded that "*the ROPSM development was viewed as an engineering approach to a physiological problem that was undertaken without the benefit of cold physiology expertise*" (Memo from Peter Tikuisis, Chair, Hypothermia Onset Panel to DARPA and USAMRMC, Oct 2, 1996). The ROPSM program was subsequently terminated on the basis of scientific and technological immaturity.

2. Thermometer pill technology

An ingestible, continuously-transmitting temperature monitoring pill developed by Johns Hopkins University (U.S. Patent 4,844,076 Lesho et al., July 4, 1989) for NASA and licensed to HQ, Inc. (www.hqinc.net/) was used in experiments to evaluate and adjust the cold water immersion safety tables for Ranger training. Thermometer pills revolutionized core temperature data collection in both the lab and field; rectal temperature probes have been a major impediment to continuous field measurements under free living conditions.

USARIEM investigators helped guide the development of thermometer pill technology, systematically performed laboratory validation of measurement accuracy against rectal and esophageal probe measurements (O'Brien et al. 1998), development of a miniaturized receiver for the first generation analog thermometer pill (partnership with DARPA and BBN Technologies), and supported the development of a digital thermometer pill (See **Table 2**). Thermometer pill technologies have been used extensively, including studies in microgravity (Dijk et al, 2001). This newer pill technology (Jonah, Equivital) gained FDA certification in 2004, further supporting its use for medical management. The current Equivital EQ02 chest-worn monitoring system includes a receiver for continuous pill temperature data acquisition. The swallowed pill typically transits the gut in 18-48 hrs. It provides valid core temperature measurements recorded by the external receiver 4 times/min, from the time it leaves the stomach (where it can still be influenced by the temperature of consumed food and drinks) (Wilkinson et al., 2008) until it is excreted.

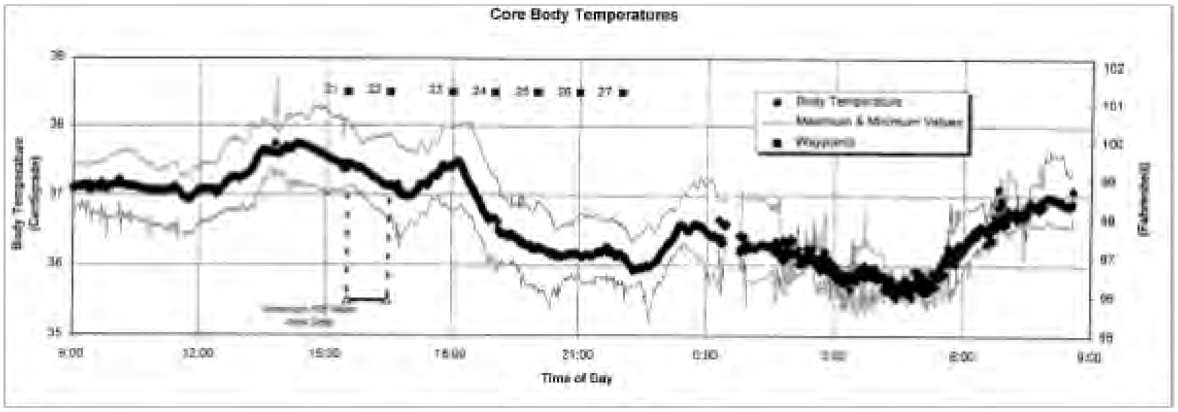

Figure 5. Body temperatures measured with temperature pills demonstrated remarkable dips during early morning for some healthy individuals in the Ranger course that would not distinguish between normal underfed Rangers and hypothermia (Hoyt et al. 1997).

Thermometer pill technology provided insights into the wider range of core body temperature fluctuations that occur in healthy Soldiers. Ranger students were monitored towards the end of their eight week winter course, where they typically lose a substantial part of their fat reserves and metabolic rate is reduced in response to underfeeding. At their normal body temperature nadir during early morning sleep, temperatures approaching 35°C were observed, even though these individuals were not suffering from a hypothermic emergency (Hoyt, Young, Matthew et al. 1997; **Figure 5**). These data were used to help validate new cold immersion guidelines for high risk training. Similar very large excursions in core body temperature were observed in Marine Corps Infantry officers monitored during field training exercises that were conducted in harsh cold and wet conditions (Hoyt, Buller, Delany et al. 2001). High core temperatures have been also been studied extensively in military training with the thermometer pill technology. A monitoring study at Fort Polk,

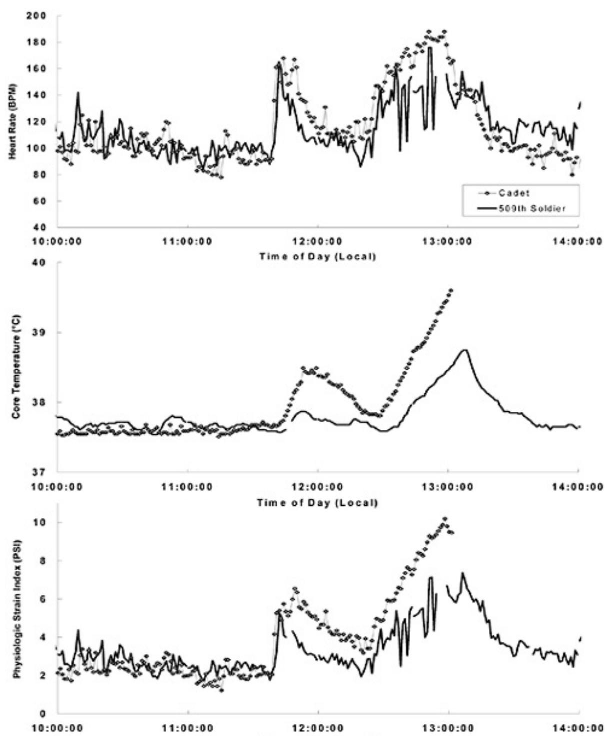

Figure 6. Comparison of responses (heart rate, core temperature, and physiological strain index) for two individuals in the same field training conditions. One individual was evacuated as a heat casualty while the other continued the training (Hoyt & Friedl, 2004).

Louisiana highlighted the importance of individual monitoring over group averages and predictions when two individuals exposed to the same environmental conditions and workload produced markedly divergent responses in thermal strain in a post hoc analysis of data (**Figure 6;** Hoyt and Friedl, 2004). Recent work has been conducted using the ingestible thermometer pill, modified to include a miniature microphone to acoustically detect heart rate and respiration rate (Traverso et al., 2015).

Collectively, the field study results demonstrate that accurate measurement of core temperature is, by itself, an inadequate predictor of individual performance limits. Some individuals continue to perform well with core body temperatures outside of previously considered "normal limits" and in temperature ranges that overlap between high performing individuals and impending thermal injury. Inclusion of other sensor data, such as heart rate, combined with body temperature, provides more reliable information about individual performance limits. This use of the Physiological Strain Index (PSI), which reflects both heat strain and work strain on a scale of 1 to 10 (Moran et al., 1988), has been successfully evaluated in field studies, including operational missions by Marines on patrol in Iraq and Afghanistan (Welles et al. 2013; Buller, Wallis, Karis et al. 2008). One "dashboard" concept using PSI as the monitored endpoint was successfully demonstrated in real time in 2000 at the Sensor Web MOUT exercise at Fort Benning for the Director, DDR&E, Dolores Etter (Hoyt et al., 2001) (**Figure 7**).

3. Predictions based on regional environmental conditions

Another effort to protect Ranger students from environmental injury included integration of local weather data from the Integrated Meteorological System (IMETS, the meteorological component of the Army Battle Command System) with individual and unit activities through the USARIEM Heat Strain Decision Aid (HSDA) in the MERCURY system, developed by Bill Matthew at USARIEM (Quarterly Report to ARPA, BBN, Jan 11, 1996). MERCURY integrated weather data with mathematical predictions of thermal strain to provide real-time, location-specific wide area assessment of thermal injury risk. The MERCURY testbed at Camp Rudder received IMETS weather data from seven remote automatic weather systems (RAWS), interpolating the data into

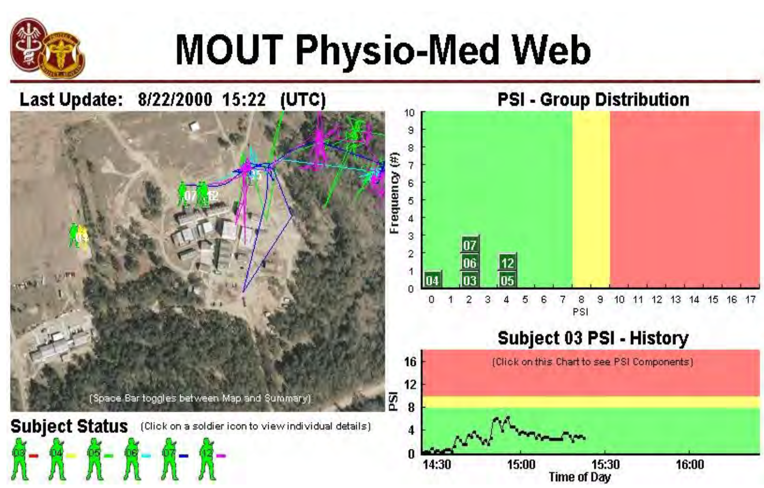

Figure 7. Real time "dashboard" display of thermal work strain of six Soldiers in the Sensor Web demonstration. The PSI scale was color coded for easy interpretation, where high PSI (red) signifies high likelihood of near term cessation of effort to cool down (Hoyt et al. 2001).

square kilometer cells to produce color coded maps of predicted thermal injury risk (green, amber, red). Three more RAWS were installed by the Ranger school along the Yellow River to monitor water depth and temperature. The MERCURY heat strain/cold survival model used air temperature, humidity, wind speed, solar radiation and water temperature and depth. The system was put in place and briefly used by the Ranger training brigade to monitor training conditions (**Figure 8**; Matthew et al. 1996, 1997). The program was terminated when DoD restrictions on the use of automated ftp file transfers was put in place.

A separate effort conducted with Rangers at Fort Benning tested an individual hydration monitoring approach for heat injury prevention. This system integrated data on fluid consumption rates from specially developed instrumented water bladders (fluid intake monitors), local weather conditions and mission contextual information, and it used the HSDA model to provide drinking alerts based on predicted appropriate consumption rates. The system performed well, but without a simultaneous measurement of fluid loss, the hydration monitoring was not sensitive enough to improve individual hydration. The most important accomplishment was the successful testing of communications strategies; no Soldier platform was available for these biomonitoring applications. This study tested a newly developed inductive personal area network (PAN) and a novel squad area network (SAN) as critical components of PSM communications, the Spartan Area Network (SPARNET). It linked a Vital Signs Detection System (Hidalgo Ltd.), including core temperature monitoring by thermometer pill, a fluid intake monitor (instrumented bladder canteen) and a wrist-worn sleep watch. The communications systems and sensors performed well (Final Report, Innovative Wireless Technologies, February 2012).

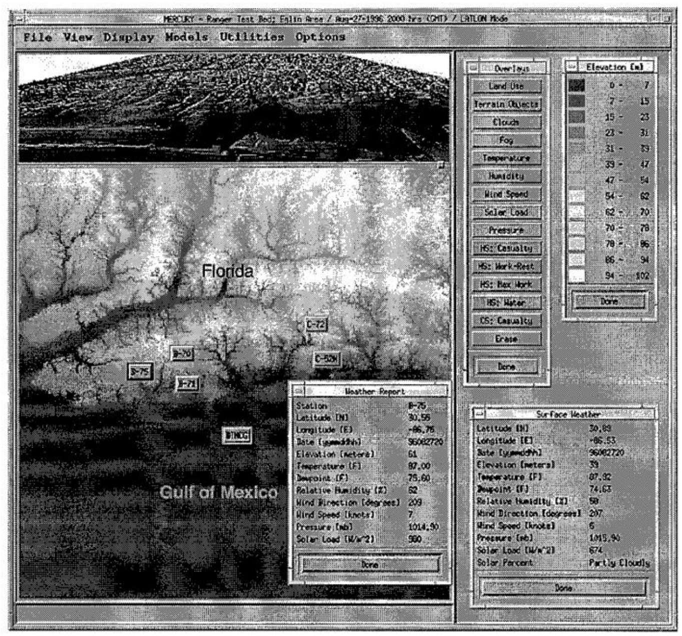

Figure 8. MERCURY map plot of zones of thermal risk for Ranger training area at Eglin AFB.

Work “Effort” Estimations and Energy Metabolism

As part of the Ranger hypothermia issue, DARPA also funded projects related to wearable sensors and geolocation. One of these projects was the BBN MicroPathfinder, a wearable communications and navigation system intended to integrate all Soldier sensors through a low power wireless system (“Body LAN”)

including acoustic anti-sniper sensors, ear microphone, compact body core temperature sensor receiver, personal inertial navigation systems, a weight monitor in the boot, an "effort" monitor, hydration monitor, computer locator radio and mission planner. USARIEM collaborations resulted in the body core temperature receiver and the foot-ground contact monitor (Quarterly Report to ARPA, BBN, Jan 11, 1996).

Richard Taylor and coworkers at the Harvard University's Concord Field Station (Taylor, 1985) predicted the energy costs associated with locomotion by using ambulatory foot contact time measurements and body weight plus any carried load. Building on this, algorithms for energy expenditure and classifying activities (e.g., run, walk, slow walk, shuffle/non-exercise activity thermogenesis, etc.) were developed and validated in the laboratory against treadmill data (Hoyt et al. 1994) and then tested in multiple field studies (Hoyt et al., 2004). Initially, foot contact devices were tested in special boot insoles in a field study with Norwegian military cadets, but the practical and cost effective solution ultimately was a pod that could be secured to boot laces on top of the foot (Contract Report, ODIC, 2002). The Army chose not to patent this technology, which allowed the inventors to patent (U.S. Patent 5,925,001; 1999) and license the technology to industry. The end result of this Army-supported effort was a commercial product (see http://www.fitlinxx.net/pebble-activity-monitor.htm).

Through the SBIR program, dead reckoning module (DRM) technologies developed in the Land Warrior program were matured and produced (http://www51.honeywell.com/aero/common/documents/myaerospacecatalog-documents/Defense_Brochures-documents/DRM4000L_Dead_Reckoning_Module.pdf). The DRM is used for navigation by foot when GPS signal availability is intermittent, for example, under a canopy when GPS signals cannot be accessed.

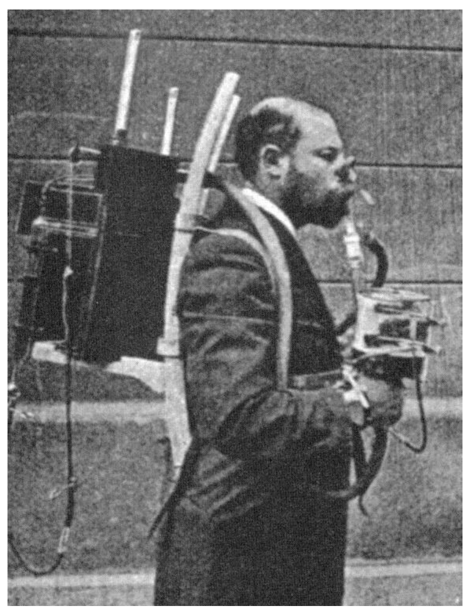

Figure 9. Ambulatory respirometer demonstrated by a German physiologist, Nathan Zuntz in 1906. A near term objective in the Army RT-PSM program is to provide a less intrusive version of the Zuntz metabolic monitoring capability.

The importance of being able to accurately estimate energy expenditure associated with locomotion (M_{loco}) is to be able to include this component of total daily energy expenditure into predictive models of metabolic energy production, metabolic heat production, heat storage, thermal load, water and energy requirements and risk of heat illness or injury. A fitness monitoring application was also developed, using the combination of foot strike data and heart rate to estimate maximum aerobic capacity, i.e., aerobic fitness (Weyand et al. 2001).

A current USARIEM collaboration with MIT Lincoln Laboratory (a Federally Funded Research Development and Engineering Center, FFRDC; www.ll.mit.edu) is focused on developing a wearable device that monitors both the energy expenditure and carbohydrate and fat utilization as metabolic fuel. This wearable device measures respiratory quotient (RQ) or, more correctly, the Respiratory Exchange Ratio (i.e., RER is the ratio of carbon dioxide production to oxygen consumption). The RQ or RER indicates the ratio of fat to carbohydrate combustion in Soldiers. This device would be an accurate, low cost, but minimally intrusive version of the respirometer developed by Nathan Zuntz over 100 years ago (**Figure 9**; Gunga & Kirsch, 1995). Accurate metabolic rate monitoring will provide foundational data for a range of predictive algorithms and physiological state analyses.

Remote Assessment of Sleep and Neurocognitive Status

In the 1980s, the Army initiated a large program targeting human performance in NBC environments, "Physiological and Psychological Effects of the NBC Environment and Sustained Operations on Systems in Combat" (P^2NBC^2). Funding from this program supported the development of a wide range of behavioral monitoring systems through the Office of Military Performance Assessment Testing (OMPAT). The initial concept was to use wrist-worn triaxial accelerometry to measure and automatically score behavior patterns, including sleep, outside of a laboratory (Redmond & Hegge, 1985). The most significant product to emerge was the WRAIR "sleep watch," developed in collaboration with an SBIR partner, PCD, Inc. (Fort Walton Beach, FL) and has been used in numerous field studies to estimate duration and patterns of sleep using the Cole-Kripke Algorithm (Cole, et al, 1992). Actigraphy is generally recognized as a valid method of estimating sleep durations (Marino et al., 2013).

The Army organized and led a state-of-the-art review of sleep model predictions of performance in 2002, including a comparison of eight leading sleep and performance models, and they concluded that the existing models were inadequate predictors of individual performance (Van Dongen, 2004). The "sleep watch" system involving assessment of recent sleep history and prediction of average performance (based on psychomotor vigilance test (PVT) responses) has not proven useful to Soldiers and leaders in the field, where the alertness status of individuals is the critical assessment needed. A variant of the sleep watch, developed collaboratively by Harris Lieberman at USARIEM, includes PVT assessment and environmental measurements, including light exposure at the wrist (Lieberman & Coffey, 1997). More recent sleep watches (e.g., BASIS Peak, Intel Corp.) are attempting to parse sleep quality beyond duration and interruptions into deep and REM sleep duration. Capturing data that provides greater detail about restorative sleep has great potential as a research tool for military field studies.

A NHRC effort using real-time assessment of EEG attempted to monitor vigilance in ship watch-standing with a concept involving dry electrode technology for the sensors built into a seaman's cap, but computing power and the dry electrode technology were both insufficiently mature (Jung et al. 1997). More recently, an IRBA effort using a

single channel EEG electrode attached to the forehead has shown promise in alertness management in French military aviators (Sauvet et al. 2014).

The OMPAT also set in motion the development of the Performance Assessment Battery involving computerization of paper-and-pencil neuropsychological assessments, and this eventually resulted in the currently used Automated Neuropsychological Assessment Metric (ANAM) and an ANAM test version (ARES) that could be administered remotely on a handheld system. Attempts to test neuropsychological and alertness fitness for duty with measurements involving pupilometry, saccadic eye movements, and slow eyelid closure were well-funded but have so far not resulted in well validated and useable technology. The concept of using physiological measures from unobtrusive wearable PSM systems to assess neurocognitive status (i.e., readiness status) of a Soldier has been difficult to achieve (Van Orden et al. 2000). However, results from the 2014 Audio/Visual Emotion Challenge and Workshop (AVEC 2014) (<depression.sspnet.eu/avec2014>) reveal rapid progress in the use of voice and facial feature recognition, processing and machine learning to analyze subjects' emotional states.

<u>Medical Casualty Detection Systems</u>

In 1999, several AMEDD leaders decided a PSM system that remotely alerted medics and leaders to casualty producing events should be produced. The Army medical research labs were directed to "*coordinate sensor and model development efforts across Combat Casualty Care and Operational Medicine research programs, in addition to the Telemedicine and Advanced Technology Research Center*" (memo from Commanding General, USAMRMC, to lab commanders, Feb 18,1999). A very large integrated research team (IPT) chaired by Col. John Obusek was established to discuss and coordinate all research efforts and USAMRMC capabilities that might relate to WPSM. Discussion in this IPT led to a requirements document developed by an Australian exchange officer, Lt. Col. Stephan Rudski and issued by the AMEDD C&S in 2001 ("Warfighter Physiological Status Monitor (WPSM) Performance Requirement Specifications for Land Warrior") (document at Appendix A).

The AMEDD C&S requirements document summarized objectives that were classified either as "immediate" or "post-product improvements" and included an integrated concept of providing information to medics for triage, as well as to Soldiers for "force health protection." Four priorities were listed as "immediate": live-dead status, hemorrhagic shock, thermal status and sleep status. The triage capability called for a new development effort that led to three main accomplishments.

The first accomplishment was the development of algorithms to classify Soldier life signs as "present," "absent" or "unknown" (Borsotto et al. 2004). However, there were concerns about misclassification and criteria for remote ascertainment of death. This was not implemented by the Army as a desired capability for Soldiers. The linkage to a fielded Army product, the Biomedical Information System–Tactical (BMIST-T) also did

not materialize, since the BMIST-T was too cumbersome and was not valued by medics, the intended users (Kaushik & Tharion, 2009).

The second accomplishment was a wearable ballistic impact detector (BIDs) that could identify signals corresponding to a bullet strike into a Soldier. It was developed but not implemented (Van Albert & Bruney, 2004). This preceded the DARPA wearable blast monitor.

The third accomplishment resulted from a yearlong effort by an acquisition trained engineer, Don Caldwell (USAMRMC'S Military Operational Medicine Research Program), interacting with the Land Warrior program engineers to include a "911 alert" capability in the Soldier system (Land Warrior Program, Raytheon contract statement of work, 22 July 1998). The concept was to have a "button" that an individual or buddy could activate to alert medics to injury, with the intent to eventually provide automatic notification triggered by a PSM system with casualty detection capabilities.

While each of these casualty detection and alert systems were viewed as important contributions by the Army medical community, the addition of a wearable system for a Soldier solely to provide this capability was not acceptable to the U.S. Army Infantry School. The increased emphasis on PSM research led to the successful development of an integrated Soldier wearable system and research tool, originally the Life Sign Detection System (LSDS), and later termed the Vital Sign Detection System (VSDS).

Integrated WPSM-Initial Capability

The AMEDD C&S requirements document supported the establishment of a new Army Technology Objective (ATO): "Warfighter Physiological Status Monitor – Initial Capability (WPSM-IC)," 2004-2006, led by COL Beau Freund. The primary objective of this ATO was to create a wearable system that integrated desired capabilities, including sensors, data processing and algorithms, and local area network communications (**Figure 10**). In collaboration with industry partners, the product was evolved through iterative development and Soldier field testing of at least five major iterative concepts. The final product in 2006 was a commercially available, FDA 510k

Figure 10. One version of integrated WPSM-IC including (1) fluid intake monitor, (2) vital signs detection system, (3) CPU hub, (4) temperature pill, and (5) actigraph (Buller et al. 2010).

certified, chest worn system, the Equivital EQ01 (Hidalgo, Ltd.), that has become a vitally important field research tool for remote physiological data acquisition.

WPSM-IC iterative field research efforts continued to drive improvements through comparisons of different technologies and form factors (e.g., chest belt, “smart” shirt, adhesive patches) and the addition of capabilities (e.g., ECG and respiratory waveforms, core temperature sensing by thermometer pill, inductive data link). Studies involved industry and academic partners, notably Welch-Allyn, Foster Miller, Zephyr, Hidalgo, Massachusetts General Hospital and CIMIT (www.cimit.org). Army review and developmental steps involved AMEDD C&S Test Board (2007), plans for integration with Land Warrior program (2008), USAMRMC advanced development review of six systems for down-select (Hidalgo EQ-01 and Zephyr Bioharness) and USAMRMC Decision Gate review (2009-2010). Field studies using the Hidalgo system provided important new data to document thermal-work strain problems in the field. Data from patrol missions by Marines in Iraq and Afghanistan (Buller, Wallis, Karis et al. 2008; Welles et al. 2013) and data from other studies, including ones the Australian Army, helped advance the development of thermal strain algorithms. A notable example is the USARIEM algorithm that estimates body core temperature from time series heart rate data, eliminating the need to use thermometer pills to track thermal strain levels (Buller et al. 2013).

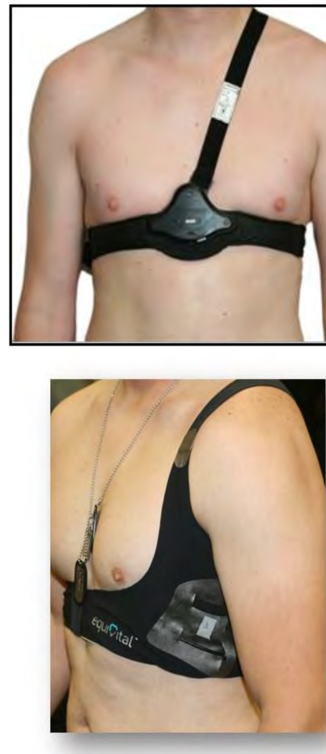

Figure 11. Soldier field-tested system improvements in the Hidalgo systems - EQ01 (top) and EQ02 (bottom).

Ultimately, Soldier acceptance of PSM systems, especially during long-duration wear in challenging field environments, was a critical determinant of actual system use. An important series of field tests on Soldier acceptance of chest-belt PSM systems were conducted by USARIEM. Several of these studies led to refinement of the systems based on Soldier feedback, including a substantive change in the design of the Hidalgo system from the EQ-01 to the EQ-02 that moved the main sensor components from the middle of the chest to the left side of the chest, out of the way of body armor (White Paper on Equivital EQ-02 development plan, Buller, Tharion & Hoyt, 2010). This second generation system improved Soldier acceptance of the chest sensors (Tharion, Buller, Potter et al. 2013) (**Figure 11**).

Making Data Useful with Thermal Monitoring Algorithms

Math modeling and validated algorithms have been keys to the development of a useful Soldier PSM system. To be useful, the system must provide actionable information and only information that is needed during training or mission execution. For the initial application of thermal strain monitoring, a variety of predictive approaches were tested, including estimations of core temperature, hydration status, physiological strain index using contextual information (e.g., ambient conditions, fitness and clothing of the individual, metabolic rate estimations, mission characteristics, etc.), core temperature, skin temperature, heart rate and other readily acquired data (**Figure 12**).

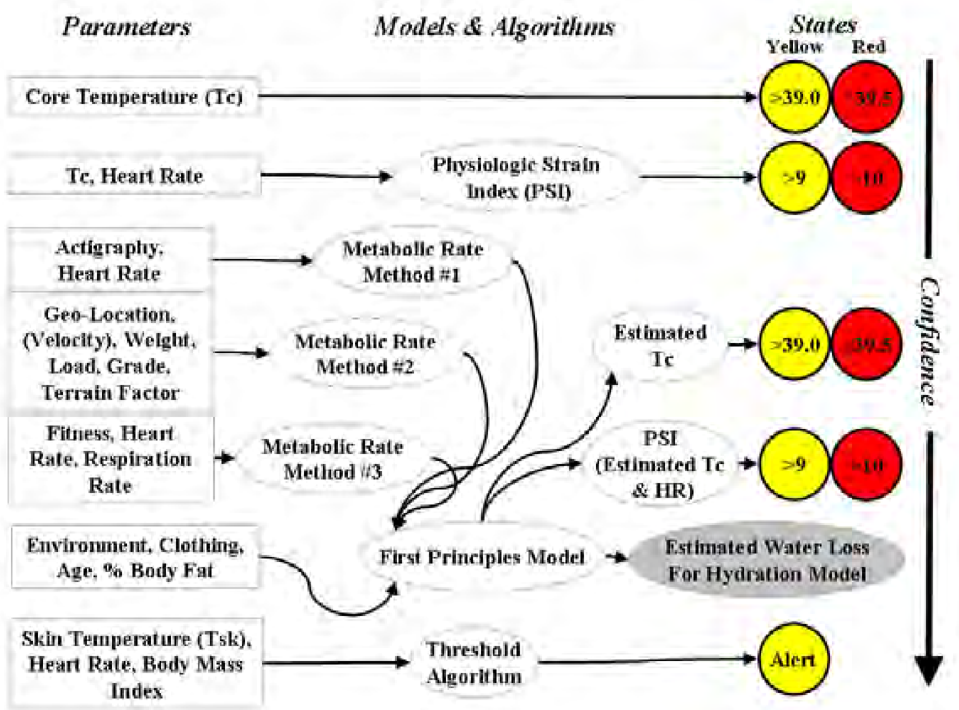

Figure 12. Model and algorithm considerations for data handling in thermal strain monitoring (Buller et al. 2010).

The most useful approach currently available is the estimation of thermal-work strain index (also known as Physiological Strain Index, PSI) (Moran et al., 2000). This 0-to-10 index has been tested in training and operational settings with various concepts of operation, ranging from regulating training intensity and providing thermal safety surveillance to possible inclusion in route planning tools for pacing and load distribution among squad members. The Army National Guard WMD-CST is an early adopter, with plans to use the system for performance and safety monitoring of encapsulated Soldiers (Buller et al. 2007; Tharion et al. 2013). Development of the Tcore algorithm, which enables Tcore prediction from time series heart rate data, makes the broad use of thermal monitoring feasible (Buller et al., 2015).

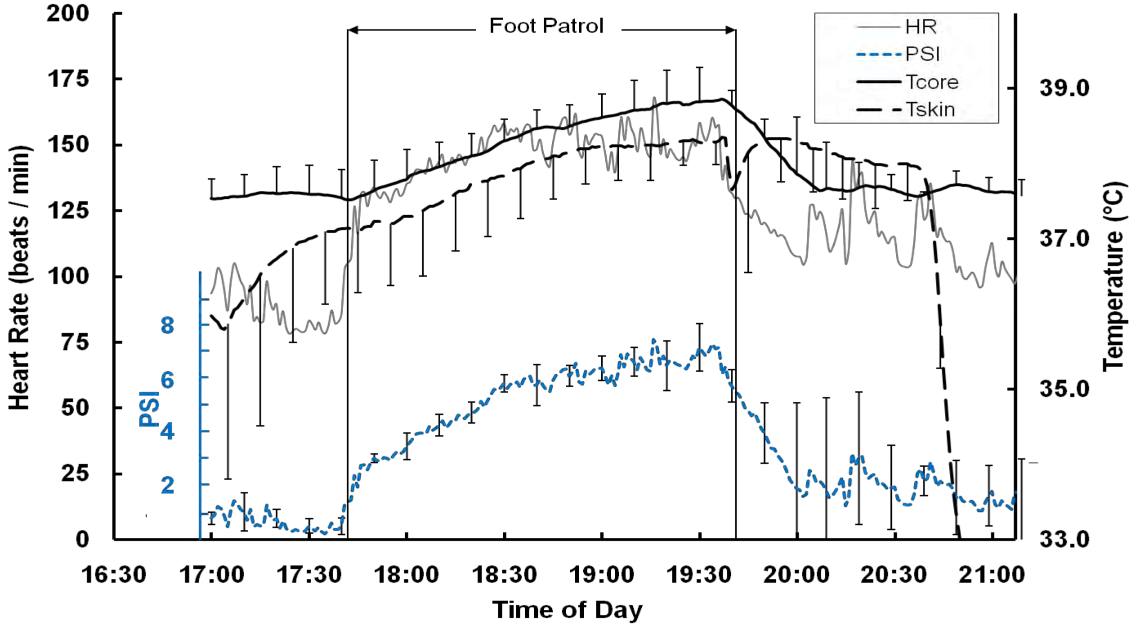

Figure 13. Actual physiological data (mean values shown) for a squad conducting a combat patrol in a hot, dry environment (Buller et al. 2008).

The current concept for information display involves a simple numerical scale (typically 0 to 10) of the thermal-work strain index, where high numbers signify a high likelihood that Soldiers are reaching a point where they will have to stop to cool down and recover. This can be color coded (green, amber, red) for further ease in information management. **Figure 13** shows mean data for a squad of men, collected during combat patrol activities in a hot, dry environment (Buller et al. 2008). These data show the progressive rise in heart rate, temperatures and thermal-work strain (PSI) index over the course of the patrol. This reflects hot but tolerable work conditions for the length of this patrol, but, presumably, a longer patrol at the same pace would further increase the thermal-work strain. Units training with these PSM systems would learn how to interpret the thermal-work strain values relative to their performance limits, either using this system for "biofeedback" training of physiological limits or continuing to use the systems in actual missions to moderate their pace of work (or work-rest cycles).

As new data sets are acquired from additional field studies, as well as from actual use of wearable sensors, thermal strain monitoring can continue to be refined, validated and expanded for other contexts (**Table 3**). New algorithms to address other Soldier status priorities (e.g., alertness and neurocognitive status; metabolic exhaustion and impending musculoskeletal injury) are currently being developed and added.

Table 3. Key PSM/WPSM Field Experiments

Study	PSM-related objective and/or accomplishment	Key outcomes	Key references
Norway Ranger Cadet Training (1996)	Activity assessment with hard wired system of in-the-boot sensors, actigraphs, geolocation, DLW	Determined field requirements for sensor durability and data streaming/time stamping	Hoyt study protocol, 1996-7; Hoyt et al., 2006
Ranger Training Brigade winter course (February 1997)	Immersion cold safety guidelines tested with thermometer pills and stored data	Characterized the wide range in normal core temp in ten healthy Rangers (35.4-39.1 °C)	Hoyt, Young, Matthew et al. 1997
Canadian infantry training and ascent of Mount Logan (1997)	Finger-worn oximetry and ESQ for early detection of altitude illnesses	Defined requirements for a less invasive continuous oximetry method	Sonna, Moulton, Hoyt et al. 2000
Infantry School/DBBL Concept Experimentation Program (CEP) – 82d Airborne (Sep 1997)	Wired PSM prototype system – temp pills, ECG hr, m-loco, geolocation, hub; small unit operations training with 20 km road march	Demonstrated value of a PSM research toolkit in Govt-acad-industry cooperative study; addressed DBBL issues	Hoyt, Buller, Redin, et al. 1997
Marine Corps Recruit Depot, Parris Island – Crucible course (1998)	Used thermometer pills to examine nutritional requirements and hypothermia risk	Characterized very high energy costs & thermoreg. responses in Crucible training	Castellani, Hoyt, Young, et al. 1998
Mount Everest ascent between Khumbu Icefalls to Camp 1 (1999)	Tested vital signs real time data transmission from climbers to base camp monitoring	Identified technology gaps in durability and connectivity for RT-PSM transmission	Harnett, Satava, et al. 2001
USMC Infantry Officer Course, Quantico, winter course (1999)	Used PSM prototype PAN data collection system with multiple sensors to characterize training stressors	Characterized responses of fit men in extreme conditions during a 10 day FTX	Hoyt, Buller, DeLany et al. 2001
MOUT attack exercise, Ft Benning, Smart Sensor Web study (2000)	Demonstrate RT-PSM capability with temp pill, hr, wireless PAN to a leader's dashboard	Showed the utility physiological strain monitoring in operations in the heat	Hoyt, Buller, Zdonik, et al. 2001
Energy Expenditure of Male and Female Sailors Aboard Ship (2002)	Develop algorithm for TDEE using pedometry against DLW during 8d cruise	Showed reasonable estimation of TDEE but vertical locomotion with ladders affects pedometry	Tharion, Yokota, Buller, DeLany & Hoyt, 2003

Study	PSM-related objective and/or accomplishment	Key outcomes	Key references
USMC Infantry Officer Course, Quantico (July 2001)	Assessed thermal burden on Marines during roadmarch with with m-loco, temp pill, ECG hr, water intake, DLW	Allayed cadre concerns about trainee heat load; validated use of m-loco sensor for energy cost and XML data management	Hoyt, Buller, Santee, et al. 2004; Yokota et al. 2004
Hot weather military readiness exercise, JRTC Fort Polk - 509th Parachute Infantry (2004)	Test PSM prototype on individuals participating in a study of nutrient-on-the- move system evaluation	Demonstrated the value of PSM in identifying (post hoc) heat casualty by PSI thermal responses during 4 hour, 20 km march	Montain, Tharion & Hoyt, 2004; Hoyt & Friedl, 2004
Vital Sign Detection System (VSDS)/WPSM-IC test, MOUT FTX, Aberdeen Proving Ground (2006)	Tested full PSM system with hydration state, thermal load, metabolic estimates, and geolocation	Refined design requirements that led to the Hidalgo EQ-01 product	Tharion study protocol, 2006
Army National Guard 95th Civil Support Team Weapons of Mass Destruction (CST-WMD) Field Study (2007)	RT-PSM performance and safety in full protective ensemble	Developed and refined the concept of operations for RT-PSM temperature monitoring in ARNG-CST	Buller, Tharion, Karis, et al. 2007
Ranger Training Brigade, Fort Benning - Spartan Data Networks (SPARNET) for RT-PSM (2008)	Monitor performance of fluid intake measurement system and squad communications with PAN and mesh network	Instrumented fluid intake systems and predicted fluid requirements were insufficiently accurate	Hoyt, 2008
Marine Rifle Squad operational patrols Iraq (Summer 2008)	PSM – thermal-work strain	Demonstrated value of monitoring on performance limits in military operations	Buller, Wallis, Karis et al. 2008
Marine Rifle Squad operational patrols Afghanistan (March 2010)	PSM – thermal-work strain	Demonstrated value of monitoring on performance limits in military operations	Welles, et al. 2013; Buller et al. 2011
Human Factors Analysis field study, 82d Airborne, Fort Bragg (2011)	Compare Hidalgo EQ-01 and EQ-02 systems for acceptability in 24 h continuous wear	Developed human factors assessment and acquired important dataset with heat injuries	Tharion et al. 2013

SUMMARY OF PSM R&D ACCOMPLISHMENTS

- Developed, commercialized, and improved an integrated wearable system was that serves as a key research tool and the foundational platform for a Soldier PSM.
- Transitioned a thermal-work strain monitoring strategy from tech base research that provides a first PSM application for Soldier use.
- Conducted an R&D program that addressed Soldier performance monitoring needs, providing a platform that can be augmented with remote medical management and force health protection capabilities in the future.
- Explored and tested communications strategies essential to remote real time PSM, including concepts for body area networks (BAN) and squad area networks (SAN).
- Developed and improved physiological sensor technology, notably the digital thermometer pill*, foot contact boot sensor*, fluid intake monitor, sleep watch*, and ballistic impact detector (*commercialized).
- Invented new concepts resulting in a wide range of intellectual property (**Table 4**), including several Army-licensed inventions.
- Tested a wide variety of other applications, with many lessons learned and foundation research for future capability development.

Table 4. Army PSM Technology Patented Accomplishments

Methodology for estimation of metabolic cost of locomotion (ILIR, 1990-93)
***References**:* Hoyt et al. 1994; Weyand et al. 2001; Tharion et al. 2004; Hoyt et al. 2004 ***Patent**:* Foot Contact Sensor System. U.S. Patent No. 5,925,001, Jul 20, 1999 (Hoyt & Lanza)
Methodology for neurobehavioral predictions from wrist worn actigraphy
References: Redmond & Hegge, 1985; Elsmore & Naitoh, 1993 ***Patents*:** Method and System for Predicting Human Cognitive Performance. U.S. Patent No. 6,553,252, Apr 22, 2003 (SECARMY); Interface for a System and Method for Evaluating Task Effectiveness based on Sleep Pattern. U.S. Patent No. 7,118,530, Oct 10, 2006 (SAIC) – ***USAMRMC licensed product*** ; Human Biovibrations Method. U.S. Patent Pending No. 2009/0149779, Sept 30, 2008 (SECARMY)
Methodology for remote neuropsychological assessment
References: Elsmore et al. 2007. ***Patents:*** System, Method, and Computer Program Product for an Automated Neuropsychological Test. U.S. Patent No. 6,669,481, Sept 2, 2010 (SECARMY); Neurocognitive and Psychomotor Performance Assessment and Rehabilitation System. U.S. Patent No. 7,837,472, Nov 23, 2010 (SECARMY) – ***USAMRMC licensed product***.

Methodology to predict physiological impact of environmental stress
References: Matthew et al. 1993; 1997 ***Patent:*** Environmental Heat Stress Monitor. U.S. Patent Pending No. 2002/0009119, Jan 24, 2002 (SECARMY)
Methodology to track water consumption and hydration
References: Tharion, Karis & Hoyt, 2009; Montain, Latzka, Hoyt & Sawka, 2002 ***Patents:*** Electronic Drink-O-Meter (DOM) to Monitor Fluid Intake and Provide Fluid Consumption Guidance. U.S. Patent Pending No. 2002/0129663, Mar 19, 2001 (SECARMY); Gear-type Drink-o-Meter to Monitor Fluid Consumption. U.S. Patent No. 7,851,775, Dec 14, 2010 (SECARMY)
Methodology to regulate personal microclimate cooling with temperature sensors
References: Cheuvront, Kolka, Cadarette, et al. 2003 ***Patent:*** Body thermoregulation using skin temperature feedback. U.S. Patent No. 7,837,723, Nov 23, 2010 (SECARMY)
Methodology to detect impacts to the body (Ballistic Impact Detection System)
References: Van Albert & Bruney, 2004 ***Patent:*** Ballistic Impact Detection System. U.S. Patent No. 7,660,692, Febr 9, 2010 (SECARMY)
Methodology for Soldier ambulatory physiologic data collection systems
References: Beidleman et al. 2003; 2004; Savell et al. 2004; Buller & Karis, 2007 ***Patent:*** Life Sign Detection and Health State Assessment System. U.S. Patent Pending No. 2014/0249430, Sept 4, 2014 (SECARMY) – ***USAMRMC licensed product;*** Apparatus and System for Monitoring. U.S. Patent Pending No. 2013/0237772, Sept 12, 2013 (Hidalgo Ltd, Cambridge)
Methodology for a magnetic induction-based personal area network system
References: Tatbul, Buller, Hoyt et al. 2004 ***Patent:*** System and Method for Short Range Wireless Communication. U.S. Patent No. 8,275,318, Sept 25, 2012 (SECARMY)
Methodology for remote core temperature estimation (heart rate method)
References: Buller et al. 2010; Buller et al. 2013 ***Patent:*** Estimation of Human Core Temperature Based on Heart Rate System and Method. U.S. Patent Pending No. 2014/0180027, June 26, 2014 (SECARMY)

SECTION 2. REQUIREMENTS AND CURRENT EFFORTS

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INTRODUCTION

Previous applied research efforts in military training and operational environments defined a set of performance issues that can be addressed by wearable PSM technologies. These efforts also produced a set of mature systems and tools that enable the data collections in field environments needed to develop and refine the performance algorithms and predictive math models. For example, these new PSM tools supported USMC evaluations of new prototype jungle uniforms that were based on actual physiological responses to realistic training over rugged Jungle Warfare Training Center Terrain (JWTC). PSM use has been an important addition used by the Australian Army investigations of thermal-work strain in loaded road marching.

Current efforts are primarily focused on transition of PSM technologies for use in military-relevant scenarios, and involve the development of concepts of operation in real environments, as well as maturation of a common Soldier wearable technology platform. These are complex issues that involve thoughtful iterative testing in realistic environments. These 6.3/6.4 RDT&E efforts fall into several categories:

- wearable system comfort, acceptability, and concepts of operation;
- wearable sensor development and maturation (e.g., photoplethysmographic sensors);
- data quality requirements to produce reliable actionable PSM information;
- data management including storage, big data tools, and metatags;
- cybersecurity in a low power tailored environment;
- signal processing and algorithm development;
- on-body, immediate area Intra Soldier Wireless PSM data transmission
- end-user device interface designs

The initial applications of RT-PSM involve thermal-work strain monitoring for: (1) short term operations involving encapsulating protective equipment, (2) training in hot environments, and (3) incorporation into route planning and pacing tools. These are the initial capabilities for real time "Soldier Readiness Score" assessment. Additional integrated Soldier readiness scores elements will include cognitive status and alertness, hydration and metabolic fuel (carbohydrate/fat) status, biomechanical status and risk of musculoskeletal injury.

REQUIREMENTS

The first comprehensive requirement for a WPSM system came from the AMEDD C&S after extensive review and discussion of available technologies and their most useful military applications (WPSM Performance Specifications, 2001; Appendix A). Since then, various studies, reviews, and wargames have articulated the potential usefulness of PSM technologies (AMEDD Transformation Workshops, RAND, 2002; Toward Affordable Systems: Portfolio Analysis and Management for Army S&T Programs, RAND, 2009). Most recently, ICDs CPDs, and CDDs have been developed and endorsed with PSM as potentially useful solutions (**Table 5**).

Table 5. Summary of Key PSM-related Requirements Documents

Document/Office/Date	PSM-related Description
Performance Requirement Specifications, Warfighter Physiological Status Monitor (WPSM), AMEDD C&S, July 2001	• Provide health and performance status data to Commanders, battalion medical staff and the combat medic • Provide Commanders with summary data about the capability status of their troops and allow optimization of their physical performance through appropriate interventions • Enable combat medic to make better decisions regarding early identification, location and triage priority and speed medical responses. id, location and triage priority and speed medical responses. [*initial* and *pre-planned product improvement* capabilities detailed]
Initial Capabilities Document, Theater Combat Casualty Care (TC3), HQDA, Oct 2007	• Advanced Casualty Locating and Remote Physiologic Monitoring
Initial Capabilities Document, Military Operational Medicine, USAMRMC, February 2008	• Continuous, real-time geographical Warfighter physiological response data collection linked to environmental data • Individual biosensors for Warfighter response to environment conditions: battle stress, non-agent toxic chemicals, heat, dehydration, battle stress response, and fatigue • Artificial Intelligence (AI) system to assess Warfighter performance capabilities, detect trends, and recommend interventions to actual or impending injuries based on real-time physiological status monitoring

Document/Office/Date	PSM-related Description
Joint Capabilities Document, Joint Force Health Protection, JROC, January 2008	• Capability to monitor health of forces engaged in military operations by using items such as: individual health status monitors; physiological sensor fusion, image analyses and diagnostic and prognostic algorithms; improved medical situational awareness interfaces
Initial Capabilities Document, Joint Force Health Protection, JROC, February 2010	• Monitor and measure factors, behaviors and psycho-motor indicators for real-time evaluation of performance degradation from stressful influences upon mission effectiveness • Provide timely, accurate information and analysis of chronic and acute health threats, risks and outcomes across the services for all military operations
Capability Develop. Document, Soldier Protection System, PEO Soldier, April 2012	• Attribute 11: Integrated Soldier Sensor System (ISSS): Work towards integration of sensors to monitor and record head accelerations, blast overpressures and physiological status…
Technical Statement of Needs, Integrated Soldier Sensor Suite, PEO Soldier, February 2013	• Physiological status information, which will be used to monitor Soldier health and safety, should include but should not be limited to heart rate, core body temperature and one or more indices of work and heat strain and risk of heat exhaustion or heat injury
Technology Transition Agreement, Real Time Physiological Status Monitoring System (RT-PSM), RAD3 and MSSPMO, April 2014	• RT-PSM will integrate new and existing thermal strain biomedical models, ultralow power sensor systems and short-range communications using a modular open architecture design • Solves current hardware problems - COTS systems are: proprietary and difficult to integrate for Soldier applications; have an unacceptable SWaP; lack military-specific human factors and are generally not suitable for tactical environments • Initial system capability provides thermal-work strain status of individuals and decision support tool for human performance enhancement and to prevent physiological failure • Provide an improved low SWaP solution that uses short range tunable narrow band wireless solution to connect leader displays
Technology Transition Agreement, USARIEM Core Temperature Estimation Algorithm, RAD3, PMO-MSS, and PEO Soldier/PM SPE, August 2014	• Specified as Government Furnished Equipment (GFE) to the ISSS prime integrator, with requirement documented by the Maneuver Center of Excellence in the Soldier Protection System Capabilities Development Document (CDD), Attribute 11 for the ISSS • Proponent has confirmed the gap exists and that a product development effort is required to fill all or part of the gap
Initial Capabilities Document, Marine Corps Expeditionary Rifle Squad, MROC, March 2015	• Develop a new light-weight monitoring capability that can be employed by the squad leader to monitor the health and fitness of his squad during extended duration operations
Endorsement of Real-Time Physiological Status Monitoring, Concepts Development Division,	• Development of a body-worn biosensor network, providing real-time health status information at an individual or squad level • The sensor will provide real-time individualized heat strain

Document/Office/Date	PSM-related Description
Maneuver Center of Excellence, October 2015	information that can be used to guide work/rest decisions, reduce risk of heat casualties, and improve overall Soldier and squad performance • This effort supports MCoE Priority Human Dimension and small unit leader development and SD Focus Area #2 Soldier integrated individual protective system

WHO ELSE IS WORKING IN THIS SPACE?

Key Partners

The current Army effort is led by USARIEM with a strong collaborating partner, MIT Lincoln Laboratory (an FFRDC; www.ll.mit.edu). Several allied military medical and human factors research groups have been involved in joint or coordinated field experiments using wearable physiological monitoring systems, notably FFI, Norway, and DSTG, Australia.

Other DoD labs

The Army Research Laboratory (ARL) has research efforts relevant to monitoring/sensing technology development, such as the acoustic physiological monitor developed by Michael Scanlon. The Human Research Effectiveness Division of ARL conducts a basic research program on EEG-based neuroimaging technologies to overcome technological barriers in the study of the human-machine interface. The Institute of Creative Technologies (http://ict.usc.edu/about/; Army University Affiliated Research Center operated by USC) conducts experiments with virtual humans that respond to physiological monitoring signals from individuals interacting with the virtual agent. This includes sophisticated models based on facial responses, as well as wearable heart rate monitoring and eye tracking to characterize emotional context.

The Navy Health Research Center (NHRC) has longstanding investments in vigilance/alertness and stress monitoring (e.g., earlier DoD vigilance and sleep research efforts led by Paul Naitoh and continuing current efforts with Scott McKeig). A newly reconstituted sleep/alertness research program includes wearable monitoring as a key element. Related research led by Nita Lewis Shattuck at the Naval Postgraduate School conducted extensive sleep monitoring in military field studies. Lastly, the Office of Naval Research supported development of a new wrist-worn sleep and activity monitor for shipboard applications.

The Air Force Research Laboratory (AFRL) is funding a research program in collaboration with universities and industry partners on the development of sweat collection devices for use in biochemical sensing.

DARPA has conducted two very significant programs related to physiological monitoring of stress and behavior. One was the Augment Cognition (AugCog) program led by

CAPT Dylan Schmorrow, which involved cognitive state assessment as a key component. The other was the Detection & Computational Analysis of Psychological Signals (DCAPS) program led by CAPT Russ Shilling which focused on the assessment of psychological health.

Combating Terrorism Technical Support Office (CTTSO)/ASD(SO/LIC) coordinates a major interagency effort on wearable/portable environmental monitoring. This is a critical sensor category designed to provide context to the physiological sensing component of RT-PSM; RT-PSM S&T will support the objectives of this office. Coordinating agencies include SOCOM, USMC, DTRA, DOE, EPA, FBI, DHS, etc. Intramural and extramural (especially SBIR-funded) programs contribute to this effort. International contracts, notably with DST Group (Melbourne) and TNO (Netherlands), have generated important data for hydration status predictive modeling and support collaborative efforts between CTTSO and USARIEM.

Other federal agencies

The National Science Foundation currently has a major multi-university program in the development of next generation wearable monitoring technology centered at the NSF Nanosystems Engineering Research Center for Advanced Self-Powered Systems of Integrated Sensors And Technologies (ASSIST) North Carolina State University North Carolina State University (https://assist.ncsu.edu/). USARIEM and MIT Lincoln Laboratory scientists are members of an external advisory board to this program.

NASA previously had a program in wearable physiological monitoring (LifeGuard; http://www.nasa.gov/centers/ames/research/technology-onepagers/life-guard.html) at NASA AMES. Current investments through the NSBRI program include development of noninvasive monitoring of intracranial pressure, with a focus on NASA's VIIP problem (vision disturbances that may signal intracerebral fluid accumulation).

NIH and VA investments have focused on monitoring during physical rehabilitation and in the detection and monitoring of behavioral symptoms associated with cognitive impairment, mood and sleep disorders in clinical settings. Other NIH research has involved activity monitoring for energy expenditure estimations, especially in weight management studies. Notably, the Army supported a three year effort by the National Center for Health Studies NHANES to collect data on activity patterns of Americans using wrist worn triaxial accelerometry.

International

Many countries have a Soldier modernization program. Many of these programs include advanced Soldier ensemble concepts with C4I capabilities that either plan for or could incorporate wearable physiological monitoring, similar to the U.S. programs in Future Force Warrior (e.g., Nett Warrior). Examples of these foreign Soldier modernization programs include: Australia (Land 200/Plan Beersheba), France (Fantassin à Équipement et Liaisons Intégrés - FÉLIN), Germany (Infanterist der

Zukunft - IdZ), Norway (Norwegian Modular Arctic Network Soldier - NORMANS), Singapore (Advanced Combat Man System - ACMS), Switzerland (Integrated and Modular Engagement System for the Swiss Soldier – IMESS) and United Kingdom (Future Integrated Soldier Technology – FIST).

The U.S. PSM research effort is coordinated with these and other countries, particularly through a NATO panel, HFM RTG-132 “Real-Time Physiological and Psycho-Physiological Status Monitoring” (Hoyt et al., 2010). A current follow-on NATO panel: HFM RTG-260 “Enhancing Warfighter Effectiveness with Wearable Bio Sensors and Physiological Models” includes active participation of members from 10 countries: Canada, France, Germany, Italy, Netherlands, Norway, Singapore, Switzerland, United Kingdom and the US.

CURRENT PSM EFFORTS

<u>Applications and Transitions of Thermal-work Strain monitoring</u>

1. Teams in protective garment encapsulation (WMD-CST, Army National Guard)

The first military adopters of PSM technology are the Army National Guard Bureau for use with Weapons of Mass Destruction Civil Support Teams (WMD-CST). The CONOPS were iteratively developed with field tests that addressed usefulness, information display strategies and communications systems (Tharion et al., 2013). The current iteration involves a modified Hidalgo EQ-02 system with the licensed Tcore from heart rate estimation algorithm and a hardwired connection to a cell phone to communicate the information off body for each operator in their protective suits. This system is being refined with Navy Naval Air Systems Command (NAVAIR) assistance with final testing by the Army Test and Evaluation Center (ATEC) before procurement and implementation.

2. Integrated Soldier Sensor System (PM Soldier Protection & Individual Equipment)

The Nett Warrior concept is a leader-integrated situational awareness system. The Integrated Soldier Sensor System (ISSS) is a component of Nett Warrior and includes transition plans for a Physiological Status Monitor capability. This is being accomplished through additional VV&A and includes field testing and post product improvements for lower SWaP, as detailed in existing TTAs between USARIEM/Military Operational Medicine research program, PMO Medical Support Systems/USAMMDA, and PEO Soldier. Current plans include a Milestone C decision by fourth quarter 2017.

3. Hot weather training environments (U.S. Marine Corps, School of Infantry-East)

Marines are innovators and early adopters of new technologies that are useful in the field. In collaboration with Mark Richter (Marine Expeditionary Rifle Squad), USARIEM and MIT Lincoln Laboratory conducted a test of the OBAN PSM system at Camp Geiger

in summer 2015 to determine how thermal-work strain monitoring would be used in a training environment. The test demonstrated how medical personnel might use such a system to monitor individuals with the highest PSI readings in order to prevent heat illness or injury. It also showed how cadre might use the system to monitor heat strain while pushing individuals with greater thermal-work tolerance, thereby providing more effective individualized training.

<u>Smaller SWaP Wearables</u>

The path to an even more lightweight PSM system with reduced power requirements (for longer duration of continuous use) is depicted in **Table 6**. These developmental efforts are funded and underway. A prototype of the low SWaP system (OBAN PSM) was the system tested in a training environment at Camp Geiger. The third generation Ultra-Low Power (ULP), body powered System-on-a-Chip (SoC), is currently in development at MIT Lincoln Lab in collaboration with PsiKick (Charlottesville, VA) and augmented by funded SBIR efforts.

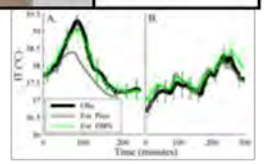
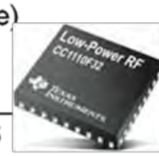
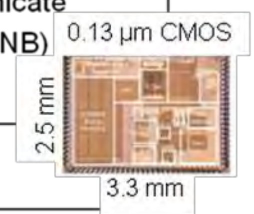
<u>Acceptability and usefulness of PSM systems</u>

As described, several studies on Soldier comfort and acceptability of the chest-worn Hidalgo systems (EQ-01, EQ-02) were conducted and reported by Tharion et al. (2013) with excellent results. The recent push to consider a wrist-worn system has put new emphasis on defining minimum requirements of sensor data accuracy, system duration/power and tactical encrypted communications.

Three studies were commissioned by PMO-MSS/USAMMDA through MIT Lincoln Lab: 1) validation of the core temperature algorithm, 2) evaluation of commercial wearable heart rate monitors and 3) a plan for the developmental testing of the Integrated Soldier Sensor System (ISSS) (Contract reports to USAMMDA, Brian Telfer et al. 2015; 2016). These evaluations defined the threshold and objective requirements for PSM systems including the first Soldier readiness metric, namely, a score for thermal-work strain.

Accurate estimation of thermal-work strain from time series measurements of heart rate requires that the wearable sensor meet minimum standards for heart rate accuracy and precision. Evaluations of currently available wrist-worn heart rate monitoring devices suggests that these technologies are still at a low TRL and are not yet capable of meeting the required level of measurement precision and accuracy. Heart rate measurements by wrist-worn systems can be improved through artifact corrections using accelerometry data, but are still insufficiently accurate at high work intensities. Current concepts for squad operations require that most Soldier worn systems operate for at least 72 hours of continuous operation without recharging; this battery life is currently not achievable with wrist-worn systems performing continuous heart rate monitoring. Nonetheless, with support from PEO Soldier, GTRI is currently conducting research and development to improve wrist-worn systems. As wearable systems mature, requirements for encryption and tactically-secure communications will add additional power and computational burdens to wearable sensor systems.

Table 6. Original concept for timeline of next generation PSM platform development. Delays in formal experimentation (e.g., SFDF-LOE) cause timeline shifts to the right but the development continues.

	Baseline (FY13)	Near-term (FY14)	Mid-term (FY15-16)
Technology	Hidalgo/Zephyr  	RT-PSM Low SWaP GOTS/mod COTS Tunable Narrow Band (TNB)(low data rate) Ti11xx 	ULPW-SoC PSM Batteryless, power harvesting, integrated sense/process/ communicate (UWB/TNB) 
TRL (current/planned)	TRL 7-8 (COTS)	TRL 4-6	TRL 3-6
Applications	ISSS – DT/HFE CB Field demo MERS – field expt	SFDF-LOE - RT PSM - PTT	EXFOR MERS
Funding	PM SPE MERS/USMC	DHP NSRDEC CERDEC PEO-Soldier	DHP NSRDEC CERDEC PEO-Soldier

Wireless PSM data transmission on and off body

The PAN and SAN communications systems, and encryption requirements, for specific fieldable systems are dictated by the system integrators, which will impact the final design of the RT-PSM. A detailed discussion of this complex topic is beyond the scope of this report. Data communication between sensors and on-body processing nodes and the communication between unit members, with their unit leader using existing long haul communications, is a focus of the Intra-Soldier Wireless, IPT (USARIEM and MIT Lincoln Lab are members). Currently, the threshold wireless communications “bubble” around an individual member is 2-3 meters. This is intended to minimize electronic signatures in a tactical environment. Various approaches are under consideration by this IPT, and the PSM is being designed to integrate with their proposed solution. In the interim, ultra-wide band and tunable narrow band strategies are being explored for PSM field testing. In training environments Bluetooth Low Energy or other commercially-derived protocols may be acceptable. For specialized applications, such as the National Guard WMD-CST teams, the PSM system is being integrated with their secure communications systems.

SECTION 3. WAY FORWARD – PSM 2030

Section 3 contents:

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    - Alertness monitoring
  - Impending Musculoskeletal Injury and Fatigue
    - Impending biomechanical injury
    - Training to limits of fatigue
    - Foot condition
  - Behavioral Status Monitoring
    - Ethography applied to human behavior
    - Voice analysis
    - Oculometrics and facial action units
  - Impending Illness
    - Prodromal symptoms and behavior inidcators
    - Volatile organic compounds and other biomarkers

NEXT GENERATION NEEDS

In response to a White House inquiry about forecasting biomedical innovations 30 years ahead, the National Institutes of Health examined the technologies that were available 30 years before and concluded that breakthrough advances 30 years ahead were likely to be based on what is currently known and available today (Elias Zerhouni, personal communication, January 2013). This observation suggests that we have identified the basic building blocks that will form the basis of foreseeable PSM systems. Our challenge is to identify and develop the technologies that best address the Army and Marine Corps needs. From a Military Operational Medicine perspective, those needs are focused on protecting health and enhancing performance.

The next steps for the PSM fall into each of the major categories of device/platform engineering, sensor technology and physiology-based algorithms. Beyond the ultra-low SWaP devices, such as the system-on-chip currently in development, there are two thrusts for general PSM platform development: 1) big data management that includes the “Internet of Things” concept and other contextual information relevant to interpreting the status of an individual; and 2) minimally invasive/implantable systems.

Big data management, exocortex, and shared sensing

A near-term expansion of current capabilities is to enhance contextual information, including systems that "learn their own Soldier." This is true "precision medicine" where genetics, individual physiology, and patterns of physiological responses collected from previous stress exposures provide more precise "readiness" indicators. This requires a significant Army investment in physiological big data management. It also requires mathematical models to provide useful readiness information from real-time assessments combined with personal contextual/historical data. These models will provide a true exocortex capability, providing automatic decision support to the individual Soldier in the context of their real-time physiological status. An extension of this big data management capability will be a longer term capability for "shared sensing" that includes enhanced environmental awareness, including emotional/physiological status of all other members of a small unit, allowing them to perform as a single organism.

At a practical level, advanced data management practices will standardize the approach to open data sharing, in part through defined and standardized data element metadata tags, and support experimentation and decision aid development by providing ready access to a wide range of data. In addition, improved data accessibility will facilitate S&T analyses and trade space assessments.

Implantables

The second mid-term thrust is to further develop the device technology and communications for implantables. The objective is a very small biocompatible PSM that can be inserted under the skin or deposited/retained on a mucosal surface (e.g., in the alimentary canal). Previously, the Army managed a large multiyear Congressional Special Interest program that significantly advanced this field when no other agency was funding "minimally invasive" physiological sensing. The MOM research program's active management of this program on "Technologies for Metabolic Monitoring" supported orphan research on the nature of biological responses to foreign materials and strategies to use natural responses to our advantage (e.g., surface coating pore sizes of 30 nm to promote incorporation instead of a foreign body rejection response). The program substantially supported novel approaches to continuous glucose sensing, providing an incubator function for research that has led to continuous glucose monitoring systems used in diabetes management today. The Army has also supported new prototype systems for completely implanted glucose monitoring systems. Research on implantables is currently a lower priority investment for intramural Army RDT&E on the basis of "enhanced mutual reliance," where the Army relies on industry to develop technology for the medical monitoring of chronic diseases and harvest the products to repurpose for PSM applications.

SENSORS AND MODELS TO ENHANCE "READINESS STATUS"

A key application of PSM is to provide Soldiers and small unit leaders with a real time assessment of the individual and unit status. The high level metric is a "Soldier Readiness Score" that can be queried for more detail about who and what if Soldier status is other than "green." Initially, RT-PSM readiness metrics are based on thermal-work strain status, but other components will add to the metric as they come on line (**Figure 14**). Thermal-work strain will also be further developed with additional refinement of the current prediction, especially with investigation of the usefulness of skin temperature and skin-core temperature gradients, as well as a large expansion into cold exposure monitoring. Monitoring performance in the cold involves hypothermia prevention, which will be based on metabolic limits with cessation of shivering and other thermal defense mechanisms as important signals in wearable monitoring. It also includes peripheral responses in the hands and feet, initially affecting critical military performance (notably manual dexterity and walking performance) and presenting injury risks with freezing cold injury to fingers and toes. Temperature monitoring in boots and gloves will be an important additional monitoring component, especially for plug-and-play cold weather mission capabilities.

Alertness and fitness for duty

1. Sleep watches and performance model predictions

The US Army Military Operational Medicine Research Program (MOMRP) has conducted sleep monitoring with wrist-worn devices since the mid 1980's. These research tools were used by USARIEM in field training studies, such as the Ranger course to document the duration of estimated sleep/inactivity. The sleep history information was used by WRAIR researchers to develop planning tools based on two process sleep models that predict typical drops in cognitive performance. Cognitive performance was assessed as throughput on computerized tests (speed x accuracy) or by a psychomotor vigilance test (PVT). The top eight sleep performance prediction models from around the world were compared in a modeling "bakeoff" organized by MOMRP in 2002, with the conclusion that more work was necessary to provide individually meaningful predictions (ASEM, 2004). Nevertheless, the WRAIR model, Fatigue Avoidance Scheduling Tool and Sleep, Activity, Fatigue, and Task Effectiveness (FAST/SAFTE) is still widely used as a mission planning tool (Hursh et al., 2004). Army leaders do not consider the information available from a standalone sleep watch as actionable mission-essential information. However, the sleep watch remains a useful field research tool. Enhanced sleep data related to quality of sleep, particularly REM and slow wave sleep duration, may be accessible with newer sleep watches using algorithms based on wrist activity plus other measures such as heart rate, core temperature, skin conductance, and skin temperature. So far, these data do not correlate well with polysomnography but may reflect alternate classifications of sleep-related physiological states that will prove important in the assessment of individual restorative sleep.

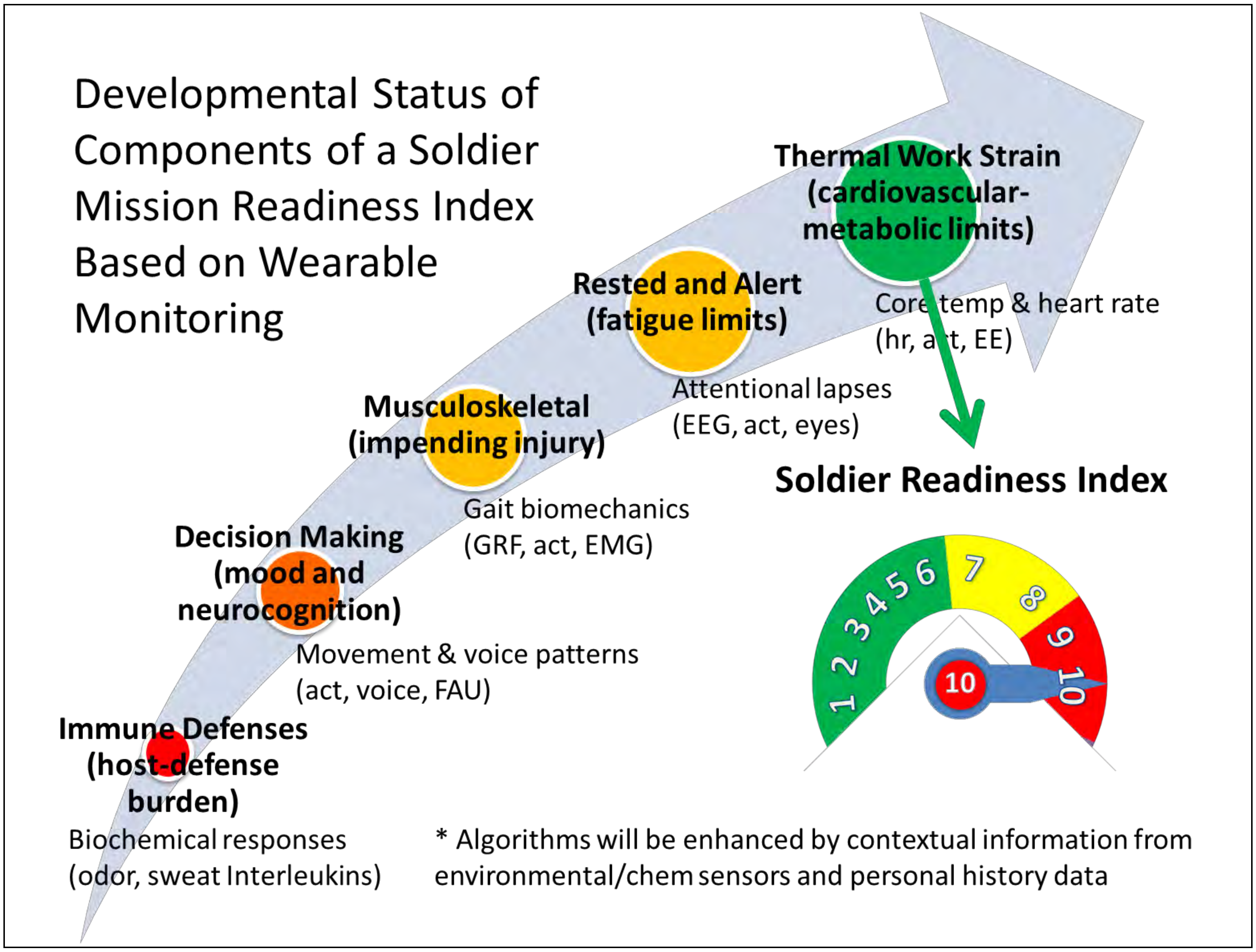


Figure 14. RT-PSM components that will contribute to a single metric: "Soldier Readiness Score." The current readiness indicator is thermal-work strain index. In the near term, alertness and physical readiness components will be part of the overall Soldier Readiness Score.

2. Alertness monitoring

Scott Mckeig at NHRC proposed the use of EEG signals to monitor readiness states of seamen, especially during critical watch standing or sentry functions. Although restricted by computing power at the time, he demonstrated how this was feasible and conceived of dry electrode technologies that would be simply built into a seaman cap to perform the monitoring functions (Jung et al. 1997). Numerous DoD SBIRs have sought to develop a workable dry electrode or other practical versions of an EEG array, but this is still at a relatively low TRL. An alternate approach has been to reduce the number of channels necessary and base alertness and lapses on a single channel EEG with electrodes secured to the forehead and behind the ear (Sauvet et al. 2014). This and related forehead sensor systems that are minimally intrusive and provide adequate data are part of the discussion in the NATO HFM 260 group, with efforts led by IRBA.

Other methods of assessing alertness were developed based on eye movements ("oculometrics") and slow eyelid closure (PERCLOSE). A large multiyear Army investment using Congressional Special Interest funding explored the use of a device that measured saccadic eye movement and pupilometry to determine fitness for duty (i.e., fatigue or drug impairment), but in multiple studies across all military services, the predictive outcomes based on this system and their proprietary algorithms were inadequate. Pupilometry as a measure of alertness showed some promise in studies at NHRC (Van Orden et al. 2000). PERCLOSE (percent of eyelid closure) was a dashboard mounted system that queries a retina and measures the amount of time that a retina cannot be detected, representing a marker of eyelid closure in a sleeping individual. The problem with this system is that the eyes of an awake individual who is gazing continuously across a panel of indicators cannot be well tracked by the eye sensor system, and no smaller system has been developed that could be mounted on eyeglasses or a helmet that moves with the individual's head movement.

<u>Impending musculoskeletal injury and fatigue</u>

1. Impending biomechanical injury

Biomechanical stressors, such as heavy loads, previous musculoskeletal injuries and even impending injury produce measureable alterations in gait (e.g., McClay, 2000; Maffiuletti et al. 2008). Some of these gait alterations have been well described for physical injury and rehabilitation, and new boot sensor technologies have advanced real time monitoring. Various shoe sensor devices were developed, including the foot strike sensor pod to characterize Soldier locomotory activity and energetics (Hoyt & Weyand, 1996). A simple Shimmer sensor (www.shimmersensing.com) attached to a standard running shoe has been the basis of the "smart shoe" to evaluate Parkinson's disease staging and progression based on pattern analysis from the multiple walking measurements (Klucken et al., 2013). Advances in this area for RT-PSM applications depend on completion of current efforts with MIT Lincoln Lab on a boot sensor insole and exploratory studies with Marines and Soldiers during road march performance. Energy expenditure and ground reaction forces, as well as gait patterns, are important components of pre-injury predictions. This is expected to be important actionable information, especially in a training environment, where "prehabilitation" in response to monitored symptoms may substantially reduce actual injury incidence and lost duty time. This is a key requirement to current Army Human Dimensions objectives including Soldier athletics initiatives and a physical readiness index with a continuous variable instead of the current simple "go-no go" scoring from a physical fitness test.

2. Training to limits of fatigue

Separate from biomechanical injury, changes in movement can also be used to assess central fatigue, mood state changes, cognitive impairment and other central nervous system alterations. Mechanisms of central fatigue and the physiological limiters of fatigue are an area of intensive study by neurophysiologists especially in connection with sports medicine. Findings in this area will guide the appropriate sensing for future

monitoring systems. In addition, real-time minimally invasive analyte sensing of lactate and other biochemical markers of exertional stress may prove to be useful.

3. Foot condition

With other sensors in the boot, it would be a major oversight not to also include temperature and humidity sensing around the foot. In cold weather operations, toe temperature could be critical actionable data. In addition, proper foot care could be monitored, based on advances made in the management and protection of feet in diabetic patients, including characteristic temperature elevation associated with tissue damage, which may be relevant to early detection of trench foot and other typical and debilitating Soldier problems.

Behavioral status monitoring

Vital information for a small unit leader is a change in behavioral status of an individual, such as a seriously depressed mood or cognitive impairment. These are states that might develop over hours or days following traumatic encounters with psychological trauma or blast exposure. These neurocognitive states could be detected by patterns of motion and additional sensing. Energy costs from movement patterns activity in Rangers has already been explored using data from the Equivital chest-worn system (Clements et al. 2012; 2013). This demonstrates the capability to acquire movement data that would also support behavioral readiness metrics.

1. Ethology applied to human behavior

How we move provides rich information about our mental and physical status, especially if normal movement patterns have been established for the individual. This science has been well developed in animal behavior research (ethology). Combined with other measures, such as speech, eye movements and facial muscle action units, monitoring of neurocognitive status has great promise. Cognitive impairment has been identified through distinctive movement patterns have been demonstrated in veterans with cognitive impairment, described by fractal math analysis of “tortuosity” of movement (Kearns et al. 2010). This is a relatively new science that has been borrowed from well-developed techniques used in wildlife biology. These examples demonstrate that easily measured motion (especially combined with speech monitoring) can provide effective indicators of mood and cognition in Soldiers. This would be important to determine impairment after military exposures, such as a IED blast or TICS and CWA.

Other aspects of movement, such as speed of movements associated with mood changes in severely depressed patients, suggest approaches that could be applied to changes from an individual’s baseline patterns to detect important mood status changes. Predictions for mood status may be substantially strengthened in combination with other sensor information, such as voice and facial expressions.

2. Voice Analysis

A least three levels of voice analysis provide information about emotional and neurocognitive status, including fundamental frequency or voice pitch, phonation and how phonemes are expressed and voice content. Voice stress analysis based on changes in fundamental frequency has been studied in an Austrian-German collaboration using special operations Soldiers in a well-developed test originally applied to Mir space station cosmonauts. Fundamental frequency corresponds to a novel emotional stress (e.g., a guerilla slide challenge) and abates with subsequent challenges, while heart rate is consistently activated as a normal response in preparation for the task.

Numerous studies have identified distinctive vocal features in patients with major depressive disease and other conditions such as bipolar disease. MIT Lincoln Lab has been on the forefront of speech analysis in neurocognitive function (Quatieri & Malyska, 2012). In combination with other measurements, speech analysis predictions of dysfunction for mild traumatic brain injury and other militarily-relevant conditions is theoretically achievable. This approach has been demonstrated by MIT Lincoln Lab using a combination of analysis of speech components and facial action units from store-and-forward data to correctly classify depressed individuals in an international competition (MIT Lincoln Laboratory, unpublished).

Verbal fluency and speaking levels can be used to track changes in cognitive status. An analysis of recorded press conferences from Presidents Reagan and Bush during their terms in office demonstrated progressive changes in word content with declining cognitive status of President Reagan (Berisha et al. 2015). Voice analysis requires communication, but certain necessary communications in military operations are a part of the analysis for individual and unit functioning where, for example, the absence of communications is an indicator of individual functioning and may also reflect unit cohesion.

3. Oculometrics and Facial Action Units

Other aspects of noninvasive behavioral assessment include systems with sensors that measure eye and face. There is a reasonable expectation that micro and nano versions of these technologies could be built into wearable systems, such as eyeglasses/protective googles or helmets, but, at least initially, the practical use will be through systems such as a laptop webcam. One concept for this application is to assess an individual Soldier during regular interactions with a virtual human/Soldier avatar “coach” or “friend.” The Institute of Creative Technologies has substantially advanced this technology in the classification of mood states by analysis of facial action units, eye movements and gaze and body activity and motion (Morency et al. 2007). Other sensing information, such as heart rate and skin conductance, has been used to provide additional information to cue more appropriate responses and reciprocation in the avatar interaction, building rapport with body position, facial expressions such as smiling and eliciting specific verbal content (Gratch et al. 2007).

<u>Impending illness</u>

1. Prodromal symptoms and behavioral indicators

Part of a readiness status assessment should be health and illness. In the event of an endemic disease infection or exposure to a biological threat agent, this could be vital information. Prediction of such illness is not only conceivable but has already been demonstrated. MIT students who agreed to participate in an experiment were monitored for every conceivably measureable behavior, such as social media exchanges, time to bed, activity patterns, etc. and an algorithm was successfully developed that predicted onset of illness from the flu before the individual was aware that they were sick. Another recent analysis of physiological data collected from implanted monitoring devices in primates exposed to biological agents successfully predicted illness hours/days in advance of typical symptomatic expression of disease (MIT Lincoln Laboratory, unpublished). This was based on measurement of physiological measurements similar to those already available through the Equivital system being used to collect data from Soldiers.

2. Volatile organic compound and other biochemical biomarkers

The Monell Chemical Senses Institute, with Army funding, has characterized the unique volatile chemicals secreted in response to a general infection and also developed a system of nanotube-based sensors for volatile organic chemicals (VOCs). Sniffers based on artificial nose technology including sophisticated pattern analysis could be important components of future RT-PSM sensing that look inward (sensing Soldier VOC production), as well as outward (as environmental detectors and dosimeters).

Additional sensor development in efforts, such as the NSF-funded ASSIST program, will make it possible to measure analytics such as TNF-alpha and other general markers of host defense responses that could be used to detect and differentiate TH1 (cellular immunity) and TH2 (humoral immunity) type responses to parasitic and infectious insults.

FINAL COMMENTS

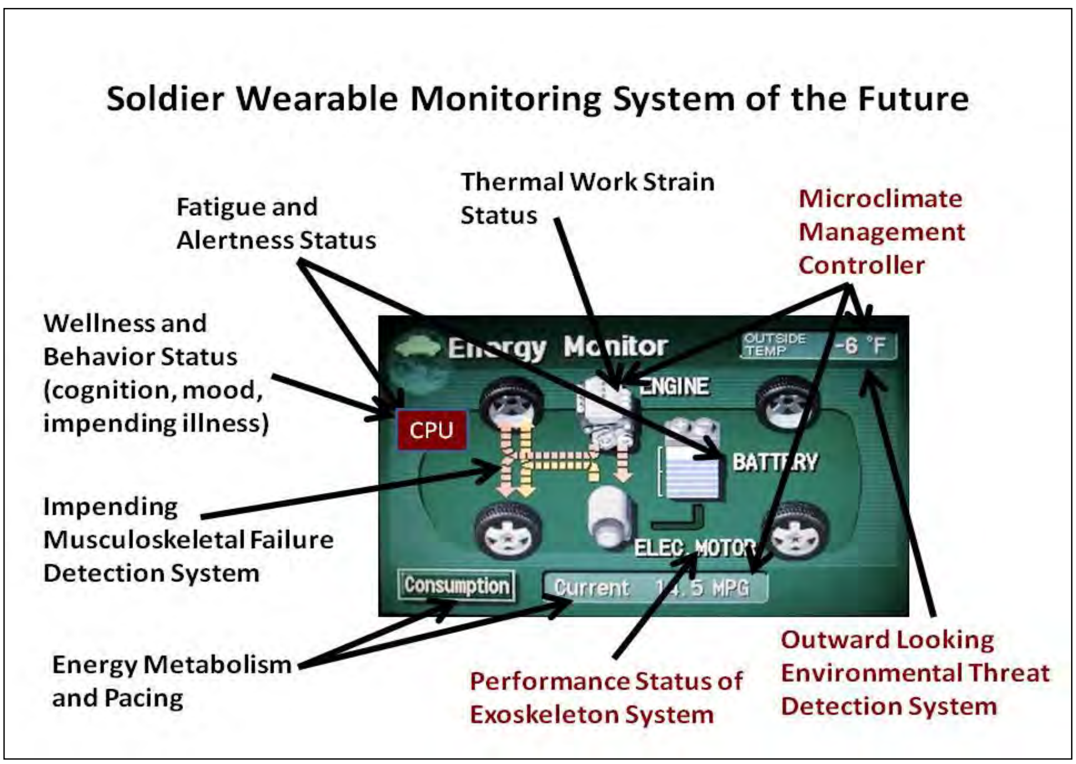
RT-PSM applications require additional platform development, especially to produce next generation ultra-low SWaP systems. Addition of other sensors and algorithms developed to produce actionable information of interest to a small unit leader will build on this platform, providing alertness and fitness for duty status monitoring, musculoskeletal injury prevention, neurocognitive status including mood and cognition and health/illness monitoring. As new sensors are developed and data acquired, many other types of useful information, such as hydration status, condition of the feet, nutritional status, etc. will also likely come available. A central guiding principal of the development effort must be iterative testing and input from the Soldier/user community, ensuring that any monitoring tool will be truly useful. For example, it is not clear that a

hydration monitor will be useful or desirable for Soldiers already well disciplined in adequate water intake, and this technology may ultimately be of greater value to field researchers and for adjustments to planning tools.

The “dashboard” display requires a different form of research that includes the users and industrial engineers. Early notional versions derived from modern vehicle dashboard displays might also include the modern soldier’s augmented capabilities such as microclimate cooling, exoskeleton, and early warning for CBRNE threats and other environmental hazards (Figure 15).

New sensors open the door to better information through improved algorithms, but sensor development is most productively driven by physiologically-based needs. For many years, the PSM program was led by the sensor technology designed for intensive care applications. Moving forward, it is important to identify the desired sensing capability and to determine what can be accomplished with existing sensors or where a new sensing strategy may be required. Pulse oximetry is an example sensor that currently exists but where a more power efficient sensing technology would be ideal for the PSM. Completely new sensing approaches may be required where there is currently no existing practical capability, such as continuous blood pressure, interstitial tissue hydration and real-time analytical measurement (e.g., biochemical markers of infection and other specific stressors).

Figure 15. Notional Soldier dashboard of the future, similar to modern car displays.



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APPENDIX A

AMEDD C&S WPSM Requirements, 2001

DEPARTMENT OF THE ARMY
U.S. ARMY MEDICAL DEPARTMENT CENTER AND SCHOOL
2250 STANLEY ROAD
FORT SAM HOUSTON, TEXAS 78234-6100

REPLY TO
ATTENTION OF

MCCS-FCC

MEMORANDUM FOR TRADOC System Manager - Soldier, U.S. Army Infantry Center, ATTN: ATZB - TS (COL W. Holton), Fort Benning, GA 31905

SUBJECT: Warfighter Physiological Status Monitor (WPSM) - Performance Specifications

1. Enclosed are the performance specifications for the WPSM. These specifications were determined after close liaison between the AMEDD combat and materiel developers and represent the desired capabilities of this product.

2. To achieve the necessary level of system integration, it may be desirable to convene an Integrated Product Team (IPT). The IPT should be comprised of members from Soldier Systems, U.S. Army Medical Research and Materiel Command, and the U.S. Army Medical Department Center and School Directorate of Combat and Doctrine Development.

3. Point of contact is LTC Stephan Rudzki, DSN 471-9337.

Encl

KEVIN C. KILEY
Major General, MC
Commanding

CF:
Commander, U.S. Army Medical Research and Materiel Command, Fort Detrick, MD 21702
Program Manager-Soldier Systems, ATTN: COL E. Johnson, 10125 Kingman Road, Fort Belvoir, VA 22060

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WARFIGHTER PHYSIOLOGICAL STATUS MONITOR (WPSM)

PERFORMANCE REQUIREMENT SPECIFICATIONS

FOR LAND WARRIOR

1. Operational Concept. The WPSM will provide health and performance status data to Commanders at various levels, battalion medical staff, and the combat medic to provide support to troops using the LWS. It will provide Commanders with summary data about the capability status of their troops and allow optimization of their physical performance through appropriate interventions. The WPSM will also enable the combat medic to make better decisions regarding the early identification, location, and triage priority of casualties and lead to reduced morbidity and mortality by speeding medical response.

2. Type of System proposed. The WPSM will be an integrated suite of physiological sensors and decision support software fully integrated into the Land Warrior System. The suite will leverage the evolutionary Land Warrior development approach in determining corresponding software and communications compatibility. This will allow for time-phased development and insertion of intended capabilities, and the addition/modification of capabilities as new requirements are identified or new solutions to existing requirements are developed. The objective sensor system must be acceptable to the soldier, convenient to use and, when incorporated into the Land Warrior system, enable the system to achieve its ORD weight reduction criteria. These characteristics will help with soldier compliance and minimize the expenditure of Command energies to enforce monitoring requirements.

3. The WPSM sensors will continuously monitor physiological parameters, but only transmit the minimum essential data to the LW computer for processing, storage and passage within the LWS. Data processing on the LW computer must be kept to the absolute minimum in order to ensure that sufficient bandwidth and CPU capacity are available for the transmission and processing of mission essential data. The WPSM sensors will have a self-test function that confirms ongoing data sampling and allows for error checking.

4. Data will be presented in two formats: (1) abnormal raw vital signs data that will be stored in the medic and BAS computers and (2) interpretative data that has been processed from physiological and physical data inputs into the indicative categories of amber (increased risk of decreased performance) and red (high risk or actual decreased performance). The measured threshold parameters will be automatically calibrated by the WPSM to an individual's normal physiological baseline.

Encl 1

Interpretative data will flow to Commanders primarily, but the squad medic and BAS will also receive this data. Data within the ranges deemed normal for an individual would not be transmitted or processed unless the relevant Commander, medic, or BAS activates a formal requirement.

5. The WPSM system must allow for the collection and exchange of data with Special Operations Forces, U.S. Marines, and Allied Forces. All software used by WPSM will be DII COE compliant and have the ability to transfer data into the TMIP databases.

6. General Characteristics. The WPSM will provide the following capabilities: [Initial (I); Pre-Planned Product Improvement (P3I)]

a. Ease of Use. The WPSM will not diminish the mobility of the wearer, and will not interfere with the wearer in performing any mission task. The system will be acceptable to the user and allow for maximal compliance that can be monitored by the command chain. The system will be non-irritating and require minimal input from the wearer.

b. Weight: The total weight of the WPSM (including sensors and any processors) must not increase the applicable Land Warrior key performance parameters. The WPSM will be integrated onto LW and will fall under a total LW weight restriction.

c. Wireless Data Transmission. The WPSM sensors will transmit data to the LW computer in a wireless manner and be fully integrated with the LW Personal Network (I).

d. FDA Approval. The WPSM systems will comply with all applicable FDA standards.

7. Remote Triage. This will be a manual process initially utilizing the available physiological data (I) but will be automated in the future, allowing the relative priority of multiple casualties to be determined automatically (P3I). The WPSM will send an auto alert to the platoon medic, squad leader and platoon sergeant when a casualty requires immediate treatment to prevent a wounded-in-action (WIA) casualty from degrading or possibility progressing to killed-in-action (KIA). The combat medic will have the ability to spot check each soldier with a query. The sensor suite data will allow the combat medic to determine if the soldier is alive or dead, and allow for the optimum priority for triage and evacuation of multiple casualties. This system will provide data sufficient to determine the likelihood of adverse outcomes in the following situations:

a. Determination of alive /dead status (I)

b. Hemorrhagic shock; initially with pulse and blood pressure (I), utilizing more sophisticated methods as they become available (P3I)

c. Respiratory distress/function (P3I)

d. Neurological function (P3I)

8. Force Health Protection monitoring. The WPSM will monitor physiological and performance status parameters to provide a Commander with data about the general condition of his troops. This will allow him to optimize the physical capabilities of his troops through appropriate interventions, thus increasing his chances of mission success. The following parameters will be measured:

a. Thermal Stress Risks. Early determination of heat and cold stress risk will allow interventions to reduce the likelihood of thermal injury. The risk index should provide an estimate of the likelihood of an individual becoming a thermal casualty within a 2-hour period. (I)

b. Hydration State. The knowledge of a soldier's hydration state will allow the accurate assessment of an individual's fluid requirements and assess the risk of cognitive and physical performance decrement. The mean percentage dehydration of an individual will be estimated to a standard deviation of 1% dehydration. (P3I)

c. Sleep Status. This capability will measure the number of hours sleep a soldier has had in the preceding 48-72 hours. Pre-determined thresholds will trigger an amber or red alert. This will allow Commanders to monitor soldiers' sleep levels and actively manage sleep/rest cycles in order to improve performance. (I)

d. Mental Alertness Status. This capability will provide risk estimates for lapses in complex mental functioning (e.g., impaired decision-making, reduced vigilance, situational awareness). Risk estimates must also be generated for the performance of key military tasks (e.g., shooting, navigation, target recognition). Measures of mental alertness will provide a broad indicator of psychological functioning. This will allow the Commander to assess the soldier's cognitive readiness and performance capability for these tasks in the operational environment. (P3I)

e. Metabolic Status/Energy Reserve. This capability will estimate metabolic status related to acute energy deficit and predict changes in body energy stores. The initial capability will estimate a soldier's daily energy balance based on activity

and estimated ration schedules. Amber and red triggers will occur when there is an increased risk of significant impairment in physical (I) and mental (P3I) performance.

f. Altitude Adaptation: This capability will determine an individual's response to the stress of altitude. Amber and red triggers will occur when an individual displays pre-determined signs of impending altitude sickness. (P3I)

g. Chemical/Biological Agent Exposure. This capability will assess a combination of physiological parameters to calculate the likelihood of having been exposed to a chemical or biological agent. Determination of adverse changes in biochemical and physiological parameters will alert commanders that there is a significant risk of adverse chem-bio exposures. (P3I)

h. Wounding Alert. This capability will trigger an alarm when the soldier sustains a penetrating or blunt wound. (P3I) The location of the wound will also be determined at a gross level. (P3I) The combat medic will use this information to provide advice to the appropriate small unit leader who will determine the appropriate action. The sensor must be able to predict the likely outcome of a wounding event with 99 percent accuracy.

9. Data exchange capability. The WPSM will be capable of transmitting raw and sensor processed data into the Land Warrior computer and to the medic, BAS, squad, platoon, company and Battalion commander. The WPSM communicates via the LWS computer, which uses joint variable message formats (JVMF) to convey information. Software that can transmit the WPSM data within the LWS is required and must not interfere with JVMF data transmission. When the WPSM sends out an alert, it will begin recording specified data on the medic's LW computer hard drive. This physiological data record must be subsequently transferred to the medic's MC4/TMIP device and recorded onto the patient's Electronic Information Carrier (EIC) prior to evacuation. The WPSM will also respond to queries from the squad leader, platoon sergeant, and company First Sergeant, as well as, the combat medic and the battalion medical staff.

10. Decision Support. The data from the sensor suite will be processed to produce meaningful information for Commanders and Battalion medical staff. The raw data must be transformed into simple condition risk states of Amber and Red. These condition states will provide the Commander and the medical staff with a real time risk assessment of performance degradation. More detailed analysis of the raw data to resolve borderline risk states may be required by the Battalion medical staff. Aggregated data will provide unit summaries of soldier status.

11. The WPSM data flow will be capable of configuration to meet unit determined SOPs. As a minimum, data must be capable of flowing as follows:

a. To the combat medic and squad leader: when the soldier has been wounded or when sensor suite exceeds pre-determined parameters.

b. To the platoon and company commander: When the predicted risk of performance decrement reaches a level pre-determined by the Commander.

c. To the Battalion commander: When previously established command interest parameters are exceeded. This will allow the Battalion commander to tailor the information he receives.

d. To Unit Surgeon: All data received by the Battalion Commander, as well as, the raw data. This will enable the staff to advise the commander on its significance.

e. To the Battalion Chaplain: In the event of a 911 call, a positive alert for wounding or death.

f. To the individual soldier: Specific alerts may be received by the soldier at the Commander's discretion, e.g., hydration status. At the completion of the mission, the soldier should have the capability to review all of his WPSM amber and red alerts.

12. Examples where information could be used directly at the squad or company level, with only secondary links to the combat medic, includes management of thermal stress, sleep/alert status and hydration state. The software suite will notify the company commander whenever the WPSM of a squad leader, platoon sergeant, or other key person in the unit exceeds defined parameters. The Unit Surgeon will be notified when the Commander's parameters exceed the normal range.